

**IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF NORTH CAROLINA
Durham Division**

VICTOR VOE, *et al.*,

Plaintiffs,

v.

THOMAS MANSFIELD, *et al.*,

Defendants.

Civil No. 1:23-cv-864

**EXPERT DECLARATION OF
ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C**

I, Armand H. Matheny Antommara, hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.
2. I have actual knowledge of the matters stated herein.
3. In preparing this declaration, I reviewed North Carolina House Bill 808 (hereafter “the ban”). In addition to this legislation and the materials cited herein, I have also relied on my years of research and other experience, as set out in my curriculum vitae (Exhibit A), in forming my opinions. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my fields of study regularly rely upon when forming opinions on subjects. I may wish to supplement these opinions or the bases for them due to new scientific research or publications, or in response to statements and issues that may arise in my area of expertise.

OVERVIEW

4. I am a pediatrician and bioethicist with extensive clinical and research experience. I am the author of 42 peer-reviewed articles, which have been published in high-impact journals including the *Journal of the American Medical Association* and *Annals of Internal Medicine*, and I direct the Ethics Center at Cincinnati Children's Hospital Medical Center. I have reviewed the ban and submit this declaration to explain my disagreement with and concerns about its provisions.

5. The ban singles out gender transition procedures, which I will refer to as gender-affirming medical care, for anomalous treatment, prohibiting healthcare professionals from providing gender-affirming medical care to minors.

6. There is no sound medical or ethical basis for the ban. The evidence for gender-affirming care is comparable to the evidence for many other treatments in pediatrics. The ban does not reflect the available scientific knowledge about the potential benefits and risks of gender-affirming medical care and ignores the reality that parents or legal guardians can provide informed consent for this medical care for their minor adolescents.

7. As a result, the ban puts clinicians in the untenable position of either following state law and violating their ethical duties to promote their patients' well-being and protect them from harm, or facing professional discipline, including revocation of their licenses, and other potential penalties. Either outcome results in harm to patients.

BACKGROUND AND QUALIFICATIONS

8. I am the Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital Medical Center ("Cincinnati Children's"). I am also a Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.

9. I received my medical degree from Washington University School of Medicine in St. Louis, Missouri in 2000. I received my PhD in Religious Ethics from The University of Chicago Divinity School in 2000. I completed my pediatrics residency at the University of Utah in 2003.

10. I have been licensed to practice medicine since 2001 and am currently licensed to practice medicine in Ohio. I have been Board Certified in General Pediatrics since 2004 and in Pediatric Hospital Medicine since the inception of this certification in 2019. I have been certified as a Healthcare Ethics Consultant since the inception of this certification in 2019.

11. I have extensive experience as a pediatrician and as a bioethicist. I have been in clinical practice since 2003 and 30% of my current effort is dedicated to caring for hospitalized patients. I was Chair of the Ethics Committee at Primary Children's Medical Center in Salt Lake City, Utah from 2005 to 2012 and have been Director of the Ethics Center at Cincinnati Children's since 2012. I regularly consult on the care of patients in the Transgender Health Clinic at Cincinnati Children's and participate in the Clinic's monthly multidisciplinary team meetings. I remain current with the medical and bioethics literature

regarding the treatment of minors with gender dysphoria. I am also part of Cincinnati Children's team that cares for patients born with differences or disorders of sex development (DSD), also known as intersex traits. I chair Cincinnati Children's Fetal Care Center's Oversight Committee, which provides the Center recommendations on the use of innovative treatments and experimental interventions.

12. I am a member of the American Academy of Pediatrics (AAP), the American Society for Bioethics and Humanities (ASBH), the Association of Bioethics Program Directors, and the Society for Pediatric Research. I was a member of the AAP Committee on Bioethics from 2005 to 2011. I have also served as a member of the ASBH's Clinical Ethics Consultation Affairs Committee from 2009 to 2014 and currently serve on its Healthcare Ethics Consultant Certification Commission.

13. I am the author of 42 peer-reviewed journal articles, 11 non-peer-reviewed journal articles, 6 book chapters, and 28 commentaries. My peer-reviewed journal articles have been published in high-impact journals, including the *Journal of the American Medical Association* and *Annals of Internal Medicine*. I am also an author of 17 policy statements and technical reports, including 4 as lead author, by the AAP.

14. I am a member of the Executive Editorial Board and the Associate Editor for Ethics Rounds of *Pediatrics*. I am an active peer reviewer for many medical journals, including the *American Journal of Bioethics* and the *Journal of Pediatrics*. I also review abstracts for meetings of professional organizations, including the Pediatric Academic

Societies and ASBH. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities*.

15. I have previously testified at deposition and trial in *Dylan Brandt, et al., v. Leslie Rutledge, et al.*, United States District Court, Eastern District of Arkansas, Case No. 5:21-CV-00450-JM-1; in the preliminary injunction phase in *Jane Doe, et al., v. Greg Abbott, et al.*, District Court of Travis County, Texas 353rd Judicial District, Case No. D-1-GN-22-000977; in the preliminary injunction phase and at deposition in *Brianna Boe, et al., and United States v. Steve Marshall, et al.*, United States District Court, Northern District of Alabama, Case No. 22-cv-184; at deposition and trial in *August Dekker, et al., v. Jason Weida, et al.*, United States District Court, Northern District of Florida, Case No. 4:22-cv-00325; and at deposition in *Kanautica Zayre-Brown vs. North Carolina Department Of Public Safety, et al.*, United States District Court, Western District of North Carolina, Case No. 3:22-cv-191.

16. I am being compensated at a rate of \$400 per hour for my work in this matter. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

GENDER DYSPHORIA IS A VALID DIAGNOSIS

17. Gender dysphoria is a diagnosis contained in the American Psychiatric Association's (APA's) *Diagnostic and Statistical Manual of Mental Disorders*.¹ The fact

¹ American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed, Text Revision. American Psychiatric Publishing; 2022.

that the diagnosis of gender dysphoria relies on patients' reports of their symptoms and is not confirmed by laboratory or radiographic testing does not undermine its validity. Many diagnoses rely on patients' reports of their symptoms and are unable to be confirmed by laboratory or radiographic testing. The diagnosis of migraine headaches, for example, depends on individuals' report of the number, duration, and characteristics of their headaches. These characteristics include the headaches' location, quality, intensity, and aggravating factors as well as the presence of nausea and/or vomiting, and light and sound sensitivity.² Like gender dysphoria, there are no confirmatory laboratory or radiographic studies for the diagnosis of migraine headaches. Radiographic studies and electroencephalograms (EEG) are only used if the history and physical examination suggest that the headache is caused by another condition, e.g., meningitis or subarachnoid hemorrhage.³ Clinical trials of migraine treatments, including randomized, double-blind/masked, placebo-controlled trials, rely on participants' daily headache diaries.⁴

² Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

³ Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care, 2nd edition. *J Headache Pain*. 2019;20(1):57.

⁴ Powers SW, Coffey CS, Chamberlin LA, et al. Trial of amitriptyline, topiramate, and placebo for pediatric migraine. *N Engl J Med*. 2017;376(2):115-124; Ailani J, Lipton RB, Goadsby PJ, et al. Atogepant for the preventive treatment of migraine. *N Engl J Med*. 2021;385(8):695-706.

THE TREATMENT OF GENDER DYSPHORIA IS SUPPORTED BY EVIDENCE COMPARABLE TO THE EVIDENCE FOR MANY OTHER MEDICAL TREATMENTS

Clinical Practice Guidelines

18. Medical professional organizations develop clinical practice guidelines to provide clinicians with helpful, evidence-based recommendations and improve patient care and outcomes. Clinical practice guidelines are developed using systematic reviews of the literature—systematic processes to select and review scientific evidence. Guidelines typically rate the quality of the evidence and grade the strength of recommendations.⁵

19. Clinical practice has different goals and methods from research or experimentation. Clinical practice's goal is to benefit individual patients and its method is individualized decision-making. Research's goal is to contribute to generalizable knowledge and research is conducted using formal protocols that describe its objectives and procedures.⁶ For example, a research study may have restrictive inclusion and exclusion criteria for participants to increase the ability of the study to draw scientifically valid conclusions. A clinician may, however, recommend a treatment to a patient who would not have been eligible for the study because the clinician believes the treatment will

⁵ American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874-877; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

⁶ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The Commission; 1978.

benefit the patient. The clinician will subsequently make recommendations about whether to continue, modify, or discontinue the treatment based on the patient's response to it.

20. In clinical practice guidelines, the quality of evidence has been defined as “the extent to which one can be confident that an estimate of effect is correct.”⁷ Quality of evidence is based on 5 factors: risk of bias, inconsistency, indirectness, imprecision, and publication bias. The Grades of Recommendation Assessment, Development and Evaluation (GRADE) system, one widely used method of grading the quality of the evidence and the strength of recommendations, distinguishes 4 levels of evidence: “high,” “moderate,” “low,” and “very low.” These levels are relative to one another and “low” does not necessarily mean poor or inadequate. As discussed below, a recommendation in a clinical practice guideline may be based on “low” or “very low” quality evidence, not just “high” or “moderate” quality evidence.⁸

21. With respect to study design, randomized trials are initially assigned to the “high” category.⁹ In a randomized trial, participants are randomly assigned to a treatment or a comparison group. The major benefit of a randomized trial is that it decreases the

⁷ Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

⁸ Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490; Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol*. 2011;64(4):383-394. The guidelines initially defined the quality of the evidence based on 4 factors, a 5th was added in a subsequent revision.

⁹ Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490; Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

likelihood that any differences in the outcomes between the groups is the result of baseline differences between the groups rather than the result of the intervention.¹⁰ Randomized trials' final rating may be lowered based on a variety of factors.¹¹

22. By comparison, observational studies are initially assigned to the “low” category.¹² Observational studies include cross-sectional and longitudinal studies. In cross-sectional studies, investigators collect data at a single point in time. Cross-sectional design permits investigators to examine potential associations between factors, but it cannot prove one factor caused the other. An example of a cross-sectional study related to gender-affirming medical care is Jack L. Turban and colleagues' analysis of data from the 2015 United States (US) Transgender Survey. The survey asked transgender adults, who were recruited through community outreach, about their demographics, past gender-affirming medical care, family support, and mental health outcomes. The investigators found that those who received pubertal suppression had lower odds of lifetime suicidal ideation compared to those who wanted treatment with pubertal suppression but did not receive it.¹³

¹⁰ Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.

¹¹ Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490; Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

¹² Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490; Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

¹³ Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*. 2020;145(2):e20191725.

In longitudinal studies, researchers follow individuals over time, making continuous or repeated measures.¹⁴ Examples of longitudinal studies include the studies of the associations between gender-affirming medical care and psychological outcomes discussed below.¹⁵ Observational studies' final rating may be increased if any of several factors is present.¹⁶

23. The labels “high” and “low” quality evidence are misleading if interpreted in the colloquial sense of “excellent or necessary” or “poor or inadequate,” respectively. While randomized controlled trials are described in the medical literature as “high” quality evidence and observational studies as “low” quality evidence, randomized controlled trials may not be ethical or feasible, may have intrinsic methodological limitations, or may be unavailable in some contexts. “Low” quality evidence can be sufficient to justify treatment recommendations.¹⁷

24. At times, it may be unethical to conduct randomized trials. For randomized

¹⁴ Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.

¹⁵ See, for example, de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

¹⁶ Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490; Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

¹⁷ Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735; Swiglo BA, Murad MH, Schunemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the Grading of Recommendations, Assessment, Development, and Evaluation System. *J Clin Endocrinol Metab*. 2008;93(3):666-673.

trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of the intervention or the control is greater. Otherwise, it would be unethical to knowingly expose trial participants to an inferior intervention or control. Trials must also be feasible; it would also be unethical to expose individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to find enough people to participate because they believe they might be randomized to an inferior intervention would be unethical because it could not produce generalizable knowledge due to an inadequate sample size.¹⁸

25. Because randomized controlled trials are frequently unavailable, systematic reviews typically find “low” or “very low”-quality evidence for most medical interventions. Padhraig S. Fleming and colleagues conducted a review of systematic reviews published on the Cochrane Database of Systematic Reviews between January 1, 2013, and June 30, 2014. They focused on those that incorporated the GRADE approach and examined the quality of evidence for the first listed primary outcome. Of the 608 reviews, 82 (13.5%) reported “high,” 197 (30.8%) “moderate,” 193 (31.7%) “low,” and 126 (24%) “very low”-quality evidence.¹⁹ In a subsequent study, a related group of

¹⁸ Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-2711.

¹⁹ Fleming PS, Koletsi D, Ioannidis JP, Pandis N. High quality of the evidence for medical and other health-related interventions was uncommon in Cochrane systematic reviews. *J Clin Epidemiol*. 2016;78:34-42. See also Howick J, Koletsi D, Ioannidis JPA, et al. Most healthcare interventions tested in Cochrane Reviews are not effective according to high quality evidence: A systematic review and meta-analysis. *J Clin Epidemiol*. 2022;148:160-169, which found that only 10.1% of interventions (158 of 1,567) had “high” quality evidence supporting their benefits.

investigators found that updated reviews did not consistently demonstrate improvements in the quality of the evidence.²⁰

26. Clinical research focusing on children is less likely to use randomized trials than is clinical research for adults. Potential reasons for this disparity include the low prevalence of childhood disease, small market share for therapeutic agents in children, low level of National Institutes of Health (NIH) funding, and difficulty enrolling children in research.²¹

27. When making recommendations, the authors of guidelines consider a variety of factors; the quality of the evidence is only one factor considered in making recommendations. Other considerations include the balance between desirable and undesirable outcomes, confidence and variability in patients' values and preferences, and resource use.²² The GRADE system distinguishes "strong" and "weak" recommendations; if the authors are highly confident in the balance between desirable and undesirable consequences, they make a "strong" recommendation and, if they are less confident, a "weak" recommendation. GRADE acknowledges that "weak" recommendations can be confused with weak evidence or misinterpreted as ignorable or uncertain

²⁰ Howick J, Koletsi D, Pandis N, et al. The quality of evidence for medical interventions does not improve or worsen: A metaepidemiological study of Cochrane reviews. *J Clin Epidemiol*. 2020;126:154-159.

²¹ Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in high quality study design. *Pediatrics*. 2008;122(1):52-57.

²² Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490; Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

recommendations. It therefore offers “conditional,” “discretionary,” and “qualified” as alternatives to “weak.”²³ The larger the differences between the desirable and undesirable consequences and the lesser the variability in patient values and preferences, the more likely a “strong” recommendation is warranted. “Low” quality evidence may be sufficient to make a “strong” recommendation.²⁴

28. Recommendations for pediatric care made by professional associations in guidelines are seldom based on well-designed and conducted randomized controlled trials due to their rarity. Instead, recommendations are frequently based on observational studies or, if such studies are unavailable, expert opinion. The medical use of the term “expert opinion” in this context refers to the consensus of experts in the relevant field(s) when studies are not available.

29. For example, of the 130 recommendations in the American Heart Association’s guideline for Pediatric Basic and Advanced Life Support, only 1 (0.8%) is based on “high-quality evidence from more than 1 [randomized clinical trial]” and 3 (2.3%) on “moderate-quality evidence from 1 or more [randomized clinical trials].” The remainder of the recommendations were based on lower quality evidence. Among its 57 “strong” recommendations (both Class 1 and Class 3 Harm), 48 (84%) are based on “limited data”

²³ Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: The significance and presentation of recommendations. *J Clin Epidemiol.* 2013;66(7):719-725.

²⁴ Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol.* 2013;66(7):726-735.

or “expert opinion.”²⁵ Table 1 (Exhibit B).

Clinical Practice Guidelines for Gender-Affirming Medical Care for Minors

30. Gender-affirming medical care is not experimental; the level of evidence supporting clinical practice guidelines recommendations regarding gender-affirming medical care for adolescents is comparable to the level of evidence supporting many other pediatric medical treatments.

31. Gender-affirming care for minors is not experimental in the colloquial or technical senses. It is not new, novel, or unproven. The first reference to the use of gonadotropin releasing hormone (GnRH) analogs, colloquially referred to as puberty blockers, for the treatment of gender dysphoria in the medical literature was in 1998, approximately 25 years ago.²⁶ Investigators began recruiting participants for prospective observational trials of GnRH analogs in 2000.²⁷ Evidence for this medical care will be discussed in greater detail below. Gender-affirming medical care is also not experimental

²⁵ Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2020;142(16_suppl_2):S469-S523. This clinical practice guideline uses different terminology than the GRADE approach for describing the quality of the evidence and the strength of recommendations. It distinguishes 3 levels of evidence and strengths of recommendations. It defines expert opinion as “consensus of expert opinion based on clinical experience.”

²⁶ Cohen-Kettenis PT, van Goozen SH. Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. *Eur Child Adolesc Psychiatry*. 1998;7(4):246-248. See also Gooren L, Delemarre-van de Waal H. The feasibility of endocrine interventions in juvenile transsexuals. *J Psychol Human Sex*. 1996;8(4):69-74.

²⁷ de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

in the technical sense; it is intended to benefit individual patients and is modified based on individual patients' responses.²⁸

32. The Endocrine Society, an international medical organization of over 18,000 endocrinology researchers and clinicians, has published a clinical practice guideline for the treatment of gender-dysphoric/gender-incongruent persons, including pubertal suppression, sex hormone treatment, and surgery for gender confirmation.²⁹ Gender-affirming medical care is also recommended by the World Professional Association for Transgender Health's (WPATH's) Standards of Care for the Health of Transgender and Gender Diverse People which is currently in its 8th version ("SOC-8").³⁰ The treatments outlined in these guidelines are also endorsed by other medical professional associations including the American Academy of Family Physicians,³¹ the AAP,³² the American

²⁸ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The Commission; 1978.

²⁹ Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

³⁰ Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

³¹ American Academy of Family Physicians. Care for the transgender and gender nonbinary patient. Accessed July 13, 2023. Available at <https://www.aafp.org/about/policies/all/transgender-nonbinary.html#:~:text=The%20American%20Academy%20of%20Family,patients%2C%20including%20children%20and%20adolescents>.

³² Rafferty J, Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence, et al. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4):e20182162.

College of Obstetricians and Gynecologists,³³ the American Medical Association,³⁴ the APA,³⁵ the American Psychological Association,³⁶ and the Pediatric Endocrine Society.³⁷

33. The Endocrine Society clinical practice guideline includes 28 recommendations: 3 (11%) are based on “moderate,” and 19 (68%) are based on “low” or “very low” quality evidence. Ten (36%) of the recommendations are “strong” and 12 (42%)

³³ American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and Committee on Health Care for Underserved Women. Health care for transgender and gender diverse individuals: ACOG Committee Opinion, Number 823. *Obstet Gynecol.* 2021;137(3):e75-e88.

³⁴ American Medical Association. Removing financial barriers to care for transgender patients H-185.950. 2022. Accessed July 13, 2023. Available at <https://policysearch.ama-assn.org/policyfinder/detail/H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml>; Madara JL to McBride B. April 26, 2021. Accessed July 13, 2023. Available at <https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-4-26-Bill-McBride-opposing-anti-trans-bills-Final.pdf>.

³⁵ American Psychiatric Association. Position statement on treatment of transgender (trans) and gender diverse youth. July 2020. Accessed July 13, 2023. Available at <https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Position-Transgender-Gender-Diverse-Youth.pdf>.

³⁶ American Psychological Association. Transgender, gender identity, and gender expression non-discrimination. August 2008. Accessed July 13, 2023, Available at <https://www.apa.org/about/policy/transgender.pdf>.

³⁷ Endocrine Society and Pediatric Endocrine Society. Transgender health: Position statement. December 2020. Accessed July 13, 2023. Available at <https://www.endocrine.org/advocacy/position-statements/transgender-health>; Anton BS. Proceedings of the American Psychological Association for the legislative year 2008: Minutes of the annual meeting of the Council of Representatives. *Am Psychol.* 2009;64:372-453.

are “weak.” The remaining 6 (21%) recommendations are Ungraded Good Practice Statements.³⁸ Table 2 (Exhibit C).

34. The quality of the evidence supporting these recommendations is similar to the quality of the evidence supporting the recommendations in other Endocrine Society clinical practice guidelines for the pediatric population. For example, none of the Endocrine Society’s 84 recommendations in its 2 other guidelines that focus on the pediatric population—guidelines on pediatric obesity and congenital adrenal hyperplasia—are based on “high” quality evidence. Twenty-four (29%) of the recommendations are based on “moderate,” and 49 (58%) on “low” or “very low” quality evidence. The remaining recommendations (11, 13%) are Ungraded Good Practice Statements.³⁹ Table 2 (Exhibit C).

35. With respect to GnRH analogs, the Endocrine Society specifically “suggest[s] that adolescents who meet diagnostic criteria for GD [gender dysphoria]/gender incongruence, fulfill criteria for treatment, . . . and are requesting treatment should initially undergo treatment to suppress pubertal development.”⁴⁰ The

³⁸ Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

³⁹ Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2018;103(11):4043-4088; Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(3):709-757.

⁴⁰ Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

evidence for this recommendation includes a longitudinal study of a group of 70 transgender adolescents who were evaluated using objective measures prior to both pubertal suppression and sex hormone treatment. The mean length of time between the start of pubertal suppression and sex hormone treatment was 1.88 years and ranged from 0.42 to 5.06 years. The study showed statistically significant decreases in behavioral and emotional problems, and depressive symptoms; and increases in general functioning.⁴¹

36. This is the same level of evidence as supports the use of GnRH analogs for the treatment of central precocious puberty which the ban permits. Central precocious puberty is the premature initiation of puberty, before 8 years of age in people assigned female at birth and before 9 in people assigned male, by the central nervous system. The potential negative effects of precocious puberty can include impairment of final adult height as well as antisocial behavior and lower academic achievement. There are no randomized trials evaluating the adult height of treated and untreated individuals. Most studies are observational and compare pretreatment, predicted final height with actual final height. These studies have additional limitations including small sample sizes.⁴² This “low” quality evidence nonetheless is sufficiently strong for the US Food and Drug Administration (FDA) to approve GnRH analogs for this indication⁴³ and for this treatment

⁴¹ de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med.* 2011;8(8):2276-2283.

⁴² Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol.* 2008;159 Suppl 1:S3-S8.

⁴³ HIGHLIGHTS OF PRESCRIBING INFORMATION. May 2017. Accessed July 13,

to become the standard of care.⁴⁴ The ban therefore subjects the use of puberty blockers to a double standard. There are no randomized clinical trials for the use of GnRH analogs to treat precocious puberty or gender dysphoria, but the evidence is deemed sufficient for the former but not the latter.

37. The evidence supporting the guideline's recommendations regarding gender-affirming hormone treatment in adolescents include Annelou L C de Vries and colleagues' longer-term follow-up of individuals after pubertal suppression through sex hormone and gender-affirming surgical treatment. Participants' mean age at their initial assessment was 13.6 years and their mean age at their final assessment was 20.7 years. The researchers report the resolution of gender dysphoria and improvement in psychological functioning.⁴⁵

38. As a result of these studies and healthcare providers' subsequent experience, randomized, placebo-controlled trials (trials that compare pharmacological treatment to no pharmacological treatment) of gender-affirming medical care are currently unethical. Potential investigators do not have equipoise between pharmacological treatment and no

2023. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020263s042lbl.pdf.

⁴⁴ Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123(4):e752-762.

⁴⁵ de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*. 2014;134(4):696-704. Additional longitudinal studies of the psychosocial effects of pubertal suppression to treat gender dysphoria include Costa R, Dunsford M, Skagerberg E, Holt V, Carmichael P, Colizzi M. Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria. *J Sex Med*. 2015;12(11):2206-2214 and Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12- to 15-year-old young people with persistent gender dysphoria in the UK. *PLoS One*. 2021;16(2):e0243894.

pharmacological treatment; they believe that pharmacological treatment is superior. It is also highly unlikely that enough participants would enroll in randomized controlled trials for them to be informative.⁴⁶

39. Even if such studies could be conducted ethically, they would provide a lower quality of evidence because of intrinsic limitations in their design. For example, it would be impossible to blind the investigators or the participants to whether the participants were receiving the active treatment or a placebo. They would know if participants were in the intervention or other control arm of the study due to the physical changes in their bodies, or the lack thereof, over time. This might bias their perception of the outcomes and lower the rating of the study's quality.⁴⁷

OFF-LABEL USE DOES NOT SUPPORT THE BAN

40. The fact that puberty blockers and gender-affirming hormone treatment are not approved by the FDA for the treatment of gender dysphoria does not support the ban. Off-label use of FDA-approved medications is legal, common, and often evidence-based. FDA approval is not required for all uses of a medication. Once the FDA has approved a medication for 1 indication,⁴⁸ thereby agreeing that it is safe (i.e., its benefits outweigh its

⁴⁶ Chew D, Anderson J, Williams K, May T, Pang K. Hormonal treatment in young people with gender dysphoria: A systematic review. *Pediatrics*. 2018;141(4):e20173742; Reisner SL, Deutsch MB, Bhasin S, et al. Advancing methods for US transgender health research. *Curr Opin Endocrinol Diabetes Obes*. 2016;23(2):198-207.

⁴⁷ Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

⁴⁸ According to the FDA, an indication includes several factors: the particular disease or

potential risks) and effective for this intended use, as is the case with the medications at issue here, prescribers are generally free to prescribe it for other indications.⁴⁹ The AAP Committee on Drugs states, “[i]t is important to note that the term ‘off-label’ does not imply an improper, illegal, contraindicated, or investigational use” and “[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient’s best interest.” It further states “in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children.”⁵⁰ There are several reasons why, even if there is substantial evidence of safety and efficacy for a new indication, one may not be approved by the FDA. The FDA is a regulatory agency which evaluates applications for approval, it does not initiate applications. Applications are

condition or the manifestation or symptoms of the disease or condition for which the drug is approved; whether the drug is approved for treatment, prevention, mitigation, cure, or diagnosis; and the population, including age group, for which the drug is safe and effective. Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services. Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products—Content and Format: Guidance for Industry. July 2018. Accessed July 13, 2023. Available at <https://www.fda.gov/files/drugs/published/Indications-and-Usage-Section-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94-Content-and-Format-Guidance-for-Industry.pdf>. A medication approved for the treatment of asthma in adults would, for example, be prescribed off label if used to treat a different disease, like pneumonia, or a different age group, like children.

⁴⁹ U.S. Food & Drug Administration. Understanding unapproved use of approved drugs “off label.” February 5, 2018. Accessed July 13, 2023. Available at <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>.

⁵⁰ Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014;133(3):563-567.

initiated by sponsors: an individual; a commercial entity, e.g., a pharmaceutical company; an organization, e.g., a patient advocacy group; or a governmental agency, e.g., an Institute of the NIH.⁵¹ A sponsor may not seek FDA approval for a new indication for a variety of reasons. Seeking approval, for example, may not be economically beneficial to the sponsor; obtaining a new indication is a costly and time-consuming process and the expense may not be offset by new revenue.⁵²

41. “Off-label” use of drugs is common in many areas of medicine, including pediatrics. For example, nafcillin, an antibiotic commonly used to treat children with invasive staphylococcal infections, such as lung or joint infections, lacks FDA approval in individuals under 18 years of age.⁵³ A recent study of children’s hospitals found that in 28.1% of encounters, at least 1 off-label drug was prescribed. Examples of medications used off-label in this study included: albuterol, which is used to treat asthma; lorazepam, which is used to treat seizures and anxiety; and lansoprazole (Prevacid®), which is used to treat gastroesophageal reflux.⁵⁴

⁵¹ Holbein ME. Understanding FDA regulatory requirements for investigational new drug applications for sponsor-investigators. *J Investig Med*. 2009;57(6):688-694.

⁵² Wittich CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. *Mayo Clin Proc*. 2012;87(10):982-990.

⁵³ Nafcillin Injection, USP. February 2007. Accessed July 13, 2023. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/050655s017lbl.pdf.

⁵⁴ See Yackey K, Stukus K, Cohen D, Kline D, Zhao S, Stanley R. Off-label medication prescribing patterns in pediatrics: An update. *Hosp Pediatr*. 2019;9(3):186-193. See also Maltz LA, Klugman D, Spaeder MC, Wessel DL. Off-label drug use in a single-center pediatric cardiac intensive care unit. *World J Pediatr Congenit Heart Surg*. 2013;4(3):262-266.

**GENERALLY APPLICABLE PRINCIPLES OF INFORMED CONSENT
APPLY TO PEDIATRIC GENDER-AFFIRMING MEDICAL CARE**

Principles of Informed Consent

42. Before performing any medical intervention, a healthcare provider must generally obtain an adult patient's informed consent. Informed consent is a process in which the provider discloses information, elicits the patient's preferences, offers medical advice, and seeks explicit authorization. To participate in the informed consent process, a patient must have medical decision-making capacity. If an adult patient lacks capacity, a proxy decision maker is generally appointed. The healthcare provider's disclosure should include the nature of the intervention and the reasons for it, as well as its potential benefits, risks, and alternatives, including the alternative of not undergoing the intervention. The patient or the patient's proxy must understand and appreciate this information and express a decision. For the informed consent to be valid, the authorization must be voluntary. Exceptions to the requirement to obtain informed consent exist, such as in the case of an emergency.⁵⁵

43. Medical decision-making and informed consent in pediatrics is more complex than in adult medicine because it involves both minor patients and their parents or legal guardians. Parents and guardians are afforded substantial, but not unlimited, discretion in making medical decisions for their minor children based on their assessment

⁵⁵ Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 6th ed. Oxford University Press; 2009.

of the individual child's best interest. They generally care about their children and best understand their children's unique needs.⁵⁶

44. Healthcare providers also have an ethical obligation to include children in medical decision-making to the extent that it is developmentally appropriate. For example, a provider examining a toddler for a possible ear infection should not ask a toddler for permission to look in the child's ear, but the provider could ask the toddler which ear the child would like to have looked in first. As a minor becomes older, the minor should participate more actively in medical decision-making and the minor's assent should be sought. In early adolescence, individuals typically have developed a sense of identity, individual values and preferences, and are developing medical decision-making capacity. Capacity entails the ability to (i) understand the indications and the potential benefits, risks, and alternatives to a treatment, including declining treatment; (ii) appreciate the implications of a treatment decision for their own lives; (iii) evaluate the potential benefits and risks; and (iv) express a preference.⁵⁷

45. The current treatment paradigm for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and assent. The Endocrine Society clinical practice guideline extensively discusses the

⁵⁶ Diekema DS. Parental refusals of medical treatment: The harm principle as threshold for state intervention. *Theor Med Bioeth.* 2004;25(4):243-264.

⁵⁷ Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics.* 2016;138(2):e20161485; Kon AA, Morrison W. Shared decision-making in pediatric practice: A broad view. *Pediatrics.* 2018;142(Suppl 3):S129-S132.

potential benefits, risks, and alternatives to treatment, and its recommendations regarding the timing of interventions are based in part on the treatment's potential risks and the adolescent's decision-making capacity. The guideline recommends that the informed consent process for puberty blockers and sex hormones include a discussion of the implications for fertility and options for fertility preservation. The Endocrine Society clinical guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes, until an adolescent is developmentally capable of providing informed consent.⁵⁸ Lieke Vrouenraets and colleagues found most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding puberty blockers.⁵⁹

Gender-Affirming Medical Care's Benefits, Risks, and Alternatives

46. The potential benefits of gender-affirming medical care include improved physical and psychological outcomes. Starting pubertal suppression in early puberty prevents adolescents with gender dysphoria from developing secondary sex characteristics inconsistent with their gender identity, which can be extremely distressing for them, and that may be difficult, if not impossible, to eliminate once the characteristics have fully developed. Sex hormone therapy results in the development of secondary sex

⁵⁸ See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

⁵⁹ Vrouenraets L, de Vries ALC, de Vries MC, van der Miesen AIR, Hein IM. Assessing medical decision-making competence in transgender youth. *Pediatrics.* 2021;148(6):e2020049643.

characteristics consistent with individuals' gender identity. Potential psychological benefits include increased quality of life and decreased depression, suicidal ideation and suicide attempts, and anxiety.⁶⁰

47. As with all medical treatments, gender-affirming medical care entails risks. One of the potential risks is negative effects on fertility but this risk should not be overstated. Puberty blockers do not, by themselves, permanently impair fertility. Children with central precocious puberty are routinely treated with puberty blockers and have typical fertility in adulthood.⁶¹ These medications are also used for fertility preservation in individuals being treated for cancer.⁶² While treatment for gender dysphoria with gender-affirming hormones may impair fertility, this is not universal and may also be reversible. There are transgender men who became pregnant while on or after discontinuing testosterone therapy.⁶³ Transgender men and women are also capable of producing eggs

⁶⁰ See, for example, Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone therapy, mental health, and quality of life among transgender people: A systematic review. *J Endocr Soc.* 2021;5(4):1-16.

⁶¹ Lazar L, Meyerovitch J, de Vries L, Phillip M, Lebenthal Y. Treated and untreated women with idiopathic precocious puberty: Long-term follow-up and reproductive outcome between the third and fifth decades. *Clin Endocrinol (Oxf).* 2014;80(4):570-576.

⁶² Valsamakis G, Valtetsiotis K, Charmandari E, Lambrinoudaki I, Vlahos NF. GnRH analogues as a co-treatment to therapy in women of reproductive age with cancer and fertility preservation. *Int J Mol Sci.* 2022;23(4):2287.

⁶³ Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. *Obstet Gynecol.* 2014;124(6):1120-1127.

and sperm respectively both during and after the discontinuation of gender-affirming hormone treatment.⁶⁴

48. Additionally, offering individuals considering gender-affirming medical care methods to potentially preserve their fertility is a component of the clinical practice guidelines discussed above.⁶⁵

49. The risk of infertility is also not unique to treatment for gender dysphoria. For example, the treatment of some nonmalignant medical conditions in children, including some rheumatologic disorders and hematologic conditions, may impair fertility.⁶⁶

50. While transgender adolescents have higher rates of depression, anxiety, suicidal ideation, and suicide attempts, there are no studies indicating that those higher rates are caused by, or exacerbated by, gender-affirming medical care.⁶⁷ Rather, contributing factors include conflict between one's appearance and identity, stigma, and

⁶⁴ Leung A, Sakkas D, Pang S, Thornton K, Resetkova N. Assisted reproductive technology outcomes in female-to-male transgender patients compared with cisgender patients: A new frontier in reproductive medicine. *Fertil Steril*. 2019;112(5):858-865; de Nie I, van Mello NM, Vlahakis E, et al. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. *Cell Rep Med*. 2023;4(1):100858.

⁶⁵ Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

⁶⁶ Hirshfeld-Cytron J, Gracia C, Woodruff TK. Nonmalignant diseases and treatments associated with primary ovarian failure: An expanded role for fertility preservation. *J Womens Health (Larchmt)*. 2011;20(10):1467-1477.

⁶⁷ Haas AP, Eliason M, Mays VM, et al. Suicide and suicide risk in lesbian, gay, bisexual, and transgender populations: Review and recommendations. *J Homosex*. 2011;58(1):10-51.

rejection.⁶⁸ As discussed above, the available evidence indicates that gender-affirming care improves, rather than worsens, psychological outcomes.

51. Finally, not knowing all potential harmful effects associated with a medication is not a sufficient reason for the FDA to not approve a medication, let alone a state to prohibit its use. The FDA requires post-marketing surveillance of medications' adverse effects because the clinical trials on which the approvals are based cannot identify all possible side effects due to the trials' size and/or duration.⁶⁹ For example, the FDA recently approved nirsevimab-alip (Beyfortus®), a monoclonal antibody, for the prevention of respiratory syncytial virus lower respiratory tract disease in babies and toddlers. Approval was based on 3 clinical trials in which 2 ,477 infants received nirsevimab-alip. These infants were followed for 361 days and continued to have the antibody present in their blood 151 days after a single intramuscular injection.⁷⁰ The rare and long-term risks will be assessed after this approval.

⁶⁸ Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: A respondent driven sampling study in Ontario, Canada. *BMC Public Health*. 2015;15:525.

⁶⁹ U.S. Food & Drug Administration. Postmarketing surveillance programs. April 2, 2020. Accessed July 13, 2023. Available at <https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs>.

⁷⁰ U.S. Food & Drug Administration. FDA approves new drug to prevent RSV in babies and toddlers. July 17, 2023. Accessed July 21, 2023. Available at <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-prevent-rsv-babies-and-toddlers>. See also Hammitt LL, Dagan R, Yuan Y, et al. Nirsevimab for prevention of RSV in healthy late-preterm and term infants. *N Engl J Med*. 2022;386(9):837-846; Domachowske J, Madhi SA, Simoes EAF, et al. Safety of Nirsevimab for RSV in infants with heart or lung disease or prematurity. *N Engl J Med*. 2022;386(9):892-894.

52. In determining whether the benefits of treatment outweigh the risks, medical providers and patients must also consider the potential alternatives including not providing or receiving the treatment. As stated above, prior to the initiation of gender-affirming medical care, many individuals with gender dysphoria have significant, unresolved symptoms that treatment improves. Without medical treatment, these symptoms would persist. The assertion that psychotherapy alone is sufficient to treat gender dysphoria in adolescents is only supported by anecdotal reports.⁷¹

The Risks and Benefits of Gender-Affirming Medical Care are Comparable to Those of Other Medical Care to which Parents and Guardians May Consent

53. Medical care for minors can require weighing potential benefits and risks in the face of uncertainty. There is nothing unique about gender-affirming medical care that justifies singling out this medical care for prohibition based on concern for adolescents' inability to assent or parents or guardians' inability to consent. Medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of adolescents, their parents or guardians, and their healthcare providers.

54. The potential risks of gender affirming medical care are comparable to the risks parents and adolescents are permitted to assume in numerous other treatment decisions, including decisions explicitly authorized by this legislation. Parents of children with some medical conditions may choose treatments that may damage, or altogether

⁷¹ See, for example, Levine SB. Transitioning back to maleness. *Arch Sex Behav*. 2018;47(4):1295-1300.

remove, their children's gonads and result in infertility.⁷² Individuals with some DSDs, such as complete androgen insensitivity syndrome, are treated with sex hormones, which have comparable risks to the use of these treatments in persons with gender dysphoria.⁷³ It is also my understanding that the ban exempts all medical care for individuals with DSDs, which would allow them to receive gender-affirming medical care, which has similar risks to this medical care in individuals who do not have DSDs. The types of risks present for breast reduction surgery, which may be performed for cosmetic reasons or to reduce physical discomfort, are similar to those of chest surgery to treat gender dysphoria.⁷⁴ Comparable surgeries performed on individuals assigned male at birth with similar, if not greater, risks include surgery for gynecomastia and pectus excavatum.⁷⁵

⁷² Delessard M, Saulnier J, Rives A, Dumont L, Rondanino C, Rives N. Exposure to chemotherapy during childhood or adulthood and consequences on spermatogenesis and male fertility. *Int J Mol Sci.* 2020;21(4):1454; Blumenfeld Z. Chemotherapy and fertility. *Best Pract Res Clin Obstet Gynaecol.* 2012;26(3):379-390; Hirshfeld-Cytron J, Gracia C, Woodruff TK. Nonmalignant diseases and treatments associated with primary ovarian failure: An expanded role for fertility preservation. *J Womens Health (Larchmt).* 2011;20(10):1467-1477; Abaci A, Catli G, Berberoglu M. Gonadal malignancy risk and prophylactic gonadectomy in disorders of sexual development. *J Pediatr Endocrinol Metab.* 2015;28(9-10):1019-1027.

⁷³ Lanciotti L, Cofini M, Leonardi A, Bertozzi M, Penta L, Esposito S. Different clinical presentations and management in complete androgen insensitivity syndrome (CAIS). *Int J Environ Res Public Health.* 2019;16(7):2168.

⁷⁴ Manahan MA, Buretta KJ, Chang D, Mithani SK, Mallalieu J, Shermak MA. An outcomes analysis of 2142 breast reduction procedures. *Ann Plast Surg.* 2015;74(3):289-292.

⁷⁵ Nordt CA, DiVasta AD. Gynecomastia in adolescents. *Curr Opin Pediatr.* 2008;20(4):375-382; Buziashvili D, Gopman JM, Weissler H, et al. An evidence-based approach to management of pectus excavatum and carinatum. *Ann Plast Surg.* 2019;82(3):352-358.

Scientific Data About Regret Do Not Support the Ban

55. The experience of regret as a result of any medical treatment is profoundly unfortunate, and individuals experiencing regret should be provided support and any additional treatment needed. However, the available scientific literature about gender-affirming medical care cannot explain why this medical care should be treated differently from all other forms of medical care nor does the data justify a prohibition of this medical care for minors.

56. While there have been anecdotal reports of regret related to gender affirming medical care, the available studies report that rates of regret are very low. For example, Chantal M. Wiepjes and colleagues report that 0.6% of transgender women and 0.3% of transgender men who had their gonads removed experienced regret.⁷⁶ Similarly, R. Hall and colleagues report regret was specifically documented in 1.1% of adult gender-diverse patients.⁷⁷ Prohibiting gender-affirming medical care to prevent regret in a small minority of patients would result in harm to the majority of patients who benefit. Support and services should nonetheless be provided to individuals who experience regret.

57. The potential for regret is also not unique to gender-affirming medical care. Ironically, at the same time that North Carolina prohibits gender-affirming medical care

⁷⁶ Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med.* Apr 2018;15(4):582-590.

⁷⁷ Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: Retrospective case-note review. *BJPsych Open.* 2021;7(6):e184.

for minors in the name of protecting vulnerable children, the statute expressly allows doctors to perform these irreversible genital surgeries on infants and children with DSDs at ages when they are unable to meaningfully participate in medical decision-making. The evidence base for these surgeries is poor and they are highly controversial when performed at such an early age.⁷⁸ Parents of children with DSDs who have authorized feminizing genitoplasty and hypospadias repair for their children have experienced regret for their decisions.⁷⁹ For example, Rachel S. Fisher and colleagues found that 38% of caregivers of female infants with congenital adrenal hyperplasia reported some level of regret about their daughter's genital surgery.

THE BAN UNDERMINES THE INTEGRITY OF THE MEDICAL PROFESSION

58. The medical profession has processes by which it evaluates treatments and determines whether they are safe and effective. The ban intervenes in this process replacing medical professionals' judgement with the judgment of the legislature. Gender-affirming medical care is consistent with professional medical standards and, as described above, it is endorsed by many medical professional associations.

⁷⁸ Jesus LE. Feminizing genioplasties: Where are we now? *J Pediatr Urol.* 2018;14(5):407-415; Frader J, Alderson P, Asch A, et al. Health care professionals and intersex conditions. *Arch Pediatr Adolesc Med.* 2004;158(5):426-428.

⁷⁹ Fisher RS, Espeleta HC, Baskin LS, et al. Decisional regret about surgical and non-surgical issues after genitoplasty among caregivers of female infants with CAH. *J Pediatr Urol.* 2022;18(1):27-33; Vavilov S, Smith G, Starkey M, Pockney P, Deshpande AV. Parental decision regret in childhood hypospadias surgery: A systematic review. *J Paediatr Child Health.* 2020;56(10):1514-1520.

59. Healthcare providers have an ethical obligation to promote their patients' well-being and to protect them from harm. When providers determine, based on their training and clinical experience, that the potential benefits of gender-affirming medical care outweigh the potential risks for a particular patient, prohibiting them from providing this treatment forces them to violate their ethical obligations to their patients or risk losing their licenses and incurring financial penalties.

CONCLUSION

60. Treating adolescents with gender dysphoria with gender-affirming medical care under clinical practice guidelines, like the Endocrine Society's, is evidence-based; its potential benefits outweigh its potential risks for many patients; and these risks are well within the range of other medical decisions that adolescents and their parents or guardians have the discretion to make in consultation with their healthcare professionals.

61. Based on my research and experience as a pediatrician and bioethicist, there is no sound medical or ethical basis to prohibit healthcare professionals from providing gender-affirming medical care to minors. Doing so puts clinicians in the untenable position of having to harm their patients and violate their integrity and ethical obligations due to the threat of losing their licenses and incurring economic penalties.

* * *

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.


Executed on: October 8, 2023 
ARMAND H. MATHENY ANTOMMARIO, MD, PhD

EXHIBIT A

Curriculum Vitae

Last Updated: October 8, 2023

PERSONAL DATA

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EDUCATION

1983-1987 BSEE	Valparaiso University, with High Distinction Valparaiso, IN
1983-1987 BS	Valparaiso University (Chemistry), with High Distinction Valparaiso, IN
1987-1989 MD	Washington University School of Medicine
1998-2000	Saint Louis, MO
1989-2000 PhD	The University of Chicago Divinity School (Religious Ethics) Chicago, IL
2000-2003 Resident	University of Utah (Pediatrics) Salt Lake City, UT
2005-2006 Certificate	Conflict Resolution Certificate Program, University of Utah Salt Lake City, UT

BOARD CERTIFICATION

2019 Pediatric Hospital Medicine, American Board of Pediatrics

2019 Healthcare Ethics Consultant-Certified, Healthcare Ethics Consultation
Certification Commission

2004 General Pediatrics, American Board of Pediatrics

PROFESSIONAL LICENSES

2012-Present Doctor of Medicine, Ohio

2006-2010 Alternative Dispute Resolution Provider—Mediator, Utah

2001-2014 Physician and Surgeon, Utah

2001-2014 Physician and Surgeon Controlled Substance, Utah

PROFESSIONAL EXPERIENCE

Full Time Positions

2019-Present *Professor*
Cincinnati Children's Hospital Medical Center, Cincinnati, OH
Department of Surgery

2019-Present *Professor of Clinical-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Surgery

2017-Present *Professor*
Cincinnati Children's Hospital Medical Center, Cincinnati, OH
Division of Pediatric Hospital Medicine

2017-Present *Professor of Clinical-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Pediatrics

2016-2017 *Associate Professor of Clinical-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Pediatrics

2012-2017 *Associate Professor*
Cincinnati Children's Hospital Medical Center, Cincinnati, OH
Division of Pediatric Hospital Medicine

2012-Present *Lee Ault Carter Chair in Pediatric Ethics*
Cincinnati Children's Hospital Medical Center

2012-2016 *Associate Professor-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Pediatrics

2010-2012 *Associate Professor of Pediatrics (with Tenure)*
University of Utah School of Medicine, Salt Lake City, UT
Divisions of Inpatient Medicine and Medical Ethics

2010-2012 *Adjunct Associate Professor of Medicine*
University of Utah School of Medicine, Salt Lake City, UT
Division of Medical Ethics and Humanities

2004-2010 *Assistant Professor of Pediatrics (Tenure Track)*
University of Utah School of Medicine, Salt Lake City, UT
Divisions of Inpatient Medicine and Medical Ethics

2004-2010 *Adjunct Assistant Professor of Medicine*
University of Utah School of Medicine, Salt Lake City, UT
Division of Medical Ethics and Humanities

2003-2004 *Instructor of Pediatrics (Clinical Track)*
University of Utah School of Medicine, Salt Lake City, UT
Divisions of Inpatient Medicine and Medical Ethics

2003-2004 *Adjunct Instructor of Medicine*
University of Utah School of Medicine, Salt Lake City, UT
Division of Medical Ethics

Part Time Positions

2023-Present *Expert Witness*, Report and Deposition
Zayre-Brown v. The North Carolina Department of Public Safety, et al.,
United States District Court, Western District of North Carolina, Case No.
3:22-CV-01910-MOC-DCK

2023-Present *Expert Witness*, Report
Poe, et al, v. Drummond, et al., United States District Court, Northern
District of Oklahoma, Case No. 23-cv-00177-JFH-SH

2023-Present *Expert Witness*, Report
L.W., et al., v. Skrmetti, et al., United States District Court, Middle
District of Tennessee, Case No. 3:23-cv-00376.

2022-Present *Expert Witness*, Reports, Deposition, and Testimony
Dekker, et al., v. Marstiller, et al., United States District Court, Northern
District of Florida, Case No. 4:22-cv-oo325-RH-MAF

2022- Present *Expert Witness*, Report, Deposition, and Testimony
Boe, et al., and United States v. Marshall, et al., United States District
Court, Middle District of Alabama Northern Division, Case No. 2:22-cv0-
184-LCB.

2022-Present *Expert Witness*, Report and Testimony
Jane Doe, et al., v. Greg Abbott, et al., District Court of Travis County,
Texas 353rd Judicial District, Case No. D-1-GN-22-000977

2021-2022 *Expert Witness*, Reports, Deposition, and Testimony
Dylan Brandt, et al., v. Leslie Rutledge, et al., United States District
Court, Eastern District of Arkansas, Case No.: 5:21-CV-00450-JM-1

2021 *Consultant*
Proctor & Gamble, Cincinnati, OH

2019 *Consultant*
Sanofi Genzyme, Cambridge, MA

2018-Present *Consultant*
Center for Conflict Resolution in Healthcare, Memphis, TN

2017-2020 *Consultant*
Amicus Therapeutics, Cranbury, NJ

2017 *Consultant*
Sarepta Therapeutics, Cambridge, MA

2014 *Consultant*
Genzyme, A Sanofi Company, Cambridge, MA

Editorial Experience

Editorial Board

2020-Present *Pediatrics*, Associate Editor for Ethics Rounds and Member of the Executive Editorial Board
2015-2020 *Journal of Clinical Ethics*
2009-2020 *Journal of Medical Humanities*

Guest Academic Editor

2017 *PLOS|ONE*

Ad Hoc Reviewer: *Academic Medicine*, *Academic Pediatrics*, *AJOB Primary Research*, *American Journal of Bioethics*, *American Journal of Law & Medicine*, *American Journal of Medical Genetics*, *American Journal of Transplantation*, *BMC Medical Ethics*, *BMJ Open*, *Canadian Journal of Bioethics*, *CHEST*, *Clinical Transplantation*, *European Journal of Human Genetics*, *European Journal of Pediatrics*, *Frontiers in Genetics*, *Hospital Medicine*, *International Journal of Health Policy and Management*, *International Journal of Nursing Studies*, *Journal of Adolescent and Young Adult Oncology*, *Journal of Clinical Ethics*, *Journal of Empirical Research on Human Research Ethics*, *Journal of General Internal Medicine*, *Journal of Healthcare Leadership*, *Journal of Hospital Medicine*, *Journal of the Kennedy Institute of Ethics*, *Journal of Law, Medicine & Ethics*, *Journal of Medical Ethics*, *Journal of Medical Humanities*, *Journal of Medicine and Life*, *Journal of Palliative Care*, *Journal of Pediatrics*, *Journal of Pediatric Surgery*, *Mayo Clinic Proceedings*, *Medicine, Healthcare and Philosophy*, *Molecular Diagnosis & Therapy*, *New England Journal of Medicine*, *Patient Preference and Adherence*, *Pediatrics*, *Pediatrics in Review*, *Personalized Medicine*, *PLOS|ONE*, *Risk Management and Healthcare Policy*, *Saudi Medical Journal*, *SSM - Qualitative Research in Health*, and *Theoretical Medicine and Bioethics*

SCHOLASTIC AND PROFESSIONAL HONORS

2023 *Digital Health Award*, Bronze Medal in the Digital Health Media/Publications category for *Pediatric Collections: Ethics Rounds: A Casebook in Pediatric Bioethics Part II*, Health Information Resource Center, Libertyville, IL
2021 *Hidden Gem Award*, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2019-2022 *Presidential Citation*, American Society for Bioethics and Humanities, Chicago, IL
2016 *Laura Mirkinson, MD, FAAP Lecturer*, Section on Hospital Medicine, American Academy of Pediatrics, Elk Grove Village, IL
2016, 2018 *Certificate of Excellence*, American Society for Bioethics and Humanities, Glenview, IL

2013, 2016	<i>Senior Resident Division Teaching Award</i> , Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012	<i>Role Model</i> , Quality Review Committee, Primary Children's Medical Center, Salt Lake City, UT
2011	<i>Member</i> , Society for Pediatric Research, The Woodlands, TX
2011	<i>Presidential Citation</i> , American Society for Bioethics and Humanities, Glenview, IL
2009	<i>Role Model</i> , Quality Review Committee, Primary Children's Medical Center, Salt Lake City, UT
2008	<i>Nominee</i> , Physician of the Year, Primary Children's Medical Center, Salt Lake City, UT
2005-2006	<i>Fellow</i> , Medical Scholars Program, University of Utah School of Medicine, Salt Lake City, UT
1995-1997	<i>Doctoral Scholar</i> , Crossroads, A Program of Evangelicals for Social Action, Philadelphia PA
1989-1992	<i>Fellow</i> , The Pew Program in Medicine, Arts, and the Social Sciences, University of Chicago, Chicago, IL

ADMINISTRATIVE EXPERIENCE

Administrative Duties

2023-Present	<i>Chair</i> , Literature Selection Technical Review Committee, National Library of Medicine, Bethesda, MD
2019-Present	<i>Chair</i> , Oversight Committee, Cincinnati Fetal Center, Cincinnati, OH
2014-Present	<i>Chair</i> , Ethics Committee, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012-Present	<i>Director</i> , Ethics Center, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012-Present	<i>Chair</i> , Ethics Consultation Subcommittee, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2010	<i>Co-Chair</i> , Ethics Subcommittee, Work Group for Emergency Mass Critical Care in Pediatrics, Centers for Disease Control and Prevention, Atlanta, GA
2009	<i>Chair</i> , Ethics Working Group, H1N1 and Winter Surge, Primary Children's Medical Center, Salt Lake City, UT
2005-2012	<i>Chair</i> , Ethics Committee, Primary Children's Medical Center, Salt Lake City, UT
2005-2012	<i>Chair</i> , Ethics Consultation Subcommittee, Primary Children's Medical Center, Salt Lake City, UT
2003-4	<i>Chair</i> , Clinical Pertinence Committee, Primary Children's Medical Center, Salt Lake City, UT

Professional & Scientific Committees

Committees

2023-Present	<i>Member</i> , Expert Committee, Humanitarian Access Program, Alnylam Pharmaceuticals, Cambridge, MA
2021	<i>Member</i> , EMCO Capacity Collaboration, Ohio Hospital Association, Columbus, OH
2020-2021	<i>Member</i> , Allocation of Scarce Resources Work Group, Ohio Hospital Association, Columbus, OH
2020-Present	<i>Member</i> , Literature Selection Technical Review Committee, National Library of Medicine, Bethesda, MD
2020	<i>Member</i> , Crisis Standards of Care Workgroup, The Health Collaborative, Cincinnati, OH
2019-Present	<i>Member</i> , Healthcare Ethics Consultant Certification Commission, Oak Park, IL
2019	<i>Member</i> , Expert Panel, Pediatric Oncology End-of-Life Care Quality Markers, Institute for Cancer Outcomes & Survivorship, University of Alabama at Birmingham, Birmingham, AL
2018	<i>Member</i> , Resource Planning and Allocation Team Implementation Task Force, Ohio Department of Health, Columbus, OH
2012-Present	<i>Member</i> , Gaucher Initiative Medical Expert Committee, Project HOPE, Millwood, VA
2009-2014	<i>Member</i> , Clinical Ethics Consultation Affairs Committee, American Society for Bioethics and Humanities, Glenview, IL
2005-2011	<i>Member</i> , Committee on Bioethics, American Academy of Pediatrics, Oak Park, IL

Data Safety and Monitoring Boards

2019-Present	<i>Member</i> , Data and Safety Monitoring Board, Sickle Cell Domestic Trials, National Heart, Lung, and Blood Institute, Bethesda, MD
2018-2019	<i>Member</i> , Standing Safety Committee for P-188-NF (Carmeseal-MD™) in Duchenne Muscular Dystrophy, Phrixus Pharmaceuticals, Inc., Ann Arbor, MI
2017-Present	<i>Member</i> , Observational Study Monitoring Board, Sickle Cell Disease Observational Monitoring Board, National Heart, Lung, and Blood Institute, Bethesda, MD
2016-2018	<i>Member</i> , Observational Study Monitoring Board, Long Term Effects of Hydroxyurea in Children with Sickle Cell Anemia, National Heart, Lung, and Blood Institute, Bethesda, MD

Reviewer	
2020-Present	<i>Abstract Reviewer</i> , American Society for Bioethics and Humanities Annual Meeting
2020	<i>Grant Reviewer</i> , The Croatian Science Foundation, Hrvatska zaklada za znanost (HRZZ)
2018	<i>Book Proposal Reviewer</i> , Elsevier
2018-2019	<i>Category Leader</i> , Religion, Culture, and Social Sciences, American Society for Bioethics and Humanities Annual Meeting
2017	<i>Timekeeper</i> , American Society for Bioethics and Humanities Annual Meeting
2017-Present	<i>Abstract Reviewer</i> , Pediatric Academic Societies Annual Meeting
2016-2021	<i>Workshop Reviewer</i> , Pediatric Academic Societies Annual Meeting
2016	<i>Grant Reviewer</i> , Innovation Research Incentives Scheme, The Netherlands Organisation for Health Research and Development
2016-2017	<i>Abstract Reviewer</i> , American Society for Bioethics and Humanities Annual Meeting
2014, 2016	<i>External Peer Reviewer</i> , PSI Foundation, Toronto, Ontario, Canada
2014	<i>Member</i> , Scientific Committee, International Conference on Clinical Ethics and Consultation
2013	<i>Abstract Reviewer</i> , American Society for Bioethics and Humanities Annual Meeting
2013	<i>Reviewer</i> , Open Research Area Plus, Agence Nationale de la Recherche, Deutsche Forschungsgemeinschaft, Economic and Social Research Council, National Science Foundation, and Organization for Scientific Research
2011-2012	<i>Abstract Reviewer</i> , Pediatric Academic Societies Annual Meeting
2011-2013	<i>Workshop Reviewer</i> , Pediatric Academic Societies Annual Meeting
2011-2014	<i>Abstract Reviewer</i> , Pediatric Hospital Medicine Annual Meeting
2011-2012	<i>Religious Studies Subcommittee Leader</i> , Program Committee, American Society for Bioethics and Humanities Annual Meeting
2010	<i>Abstract Reviewer</i> , American Society for Bioethics and Humanities Annual Meeting
Other	
2023	<i>Member</i> , Student Paper Committee, American Society for Bioethics and Humanities
2021	<i>Timekeeper</i> , American Society for Bioethics and Humanities Annual Meeting
2021	<i>Mentor</i> , Early Career Advisor Professional Development Track, American Society for Bioethics and Humanities.
2021	<i>Mentor</i> , Early Career Advisor Paper or Project Track, American Society for Bioethics and Humanities.

2109	<i>Mentor, Early Career Advising Program, American Society for Bioethics and Humanities</i>
2018	<i>Passing Point Determination, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission</i>
2018	<i>Member, Examination Committee, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission</i>
2018	<i>Item Writer, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission</i>

UNIVERSITY COMMUNITY ACTIVITIES

Cincinnati Children's Hospital Medical Center

2023-Present	<i>Member, Artificial Intelligence Governance Council</i>
2023-Present	<i>Member, Executive Committee, Discover Together Biobank</i>
2020-Present	<i>Member, Faculty Diversity and Inclusion Steering Committee</i>
2020-Present	<i>Member, Medical Management of COVID-19 Committee</i>
2020-2021	<i>Member, Caregiver Refusal Team</i>
2020-2021	<i>Member, COVID-19 Vaccine Allocation Committee</i>
2020	<i>Member, Personal Protective Equipment Subcommittee of the COVID-19 Steering Committee</i>
2018-2019	<i>Member, Planning Committee, Center for Clinical & Translational Science & Training Research Ethics Conference</i>
2017-Present	<i>Member, Donor Selection Committee</i>
2017-2020	<i>Member, Employee Emergency Fund Review Committee</i>
2017	<i>Member, Root Cause Analysis Team</i>
2016-2017	<i>Member, Planning Committee, Center for Clinical & Translational Science & Training Research Ethics Conference</i>
2015-2019	<i>Member, Destination Excellence Medical Advisory Committee</i>
2015-Present	<i>Member, Disorders of Sexual Development Case Review Committee</i>
2015-2019	<i>Member, Destination Excellence Case Review Committee</i>
2014-2018	<i>Member, Genomics Review Group, Institutional Review Board</i>
2014-2017	<i>Member, Center for Pediatric Genomics Leadership Committee</i>
2013-2017	<i>Member, Genetic Testing Subcommittee, Health Network</i>
2013-2016	<i>Member, Schwartz Center Rounds Planning Committee</i>
2013-2014	<i>Member, Genomics Ad Hoc Subcommittee, Board of Directors</i>
2012-Present	<i>Member, Cincinnati Fetal Center Oversight Committee</i>
2012-Present	<i>Member, Ethics Committee</i>
2012-Present	<i>Member, G-23</i>
2012-2016	<i>Member, Integrated Solid Organ Transplant Steering Committee</i>

University of Utah

2009-2012	<i>Member, Consolidated Hearing Committee</i>
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University of Utah School of Medicine

- 2010-2012 *Member, Medical Ethics, Humanities, and Cultural Competence Thread Committee*
- 2008-2010 *Member, Fourth Year Curriculum Committee*

University of Utah Department of Pediatrics

- 2010-2011 *Member, Planning Committee, 25th Annual Biological Basis of Children's Health Conference, "Sex, Gender, and Sexuality"*
- 2009-2012 *Member, Medical Executive Committee*
- 2005-2012 *Member, Retention, Promotion, and Tenure Committee*
- 2004-2012 *Interviewer, Residency Program*
- 2003-2012 *Member, Education Committee*

Intermountain Healthcare

- 2009-2012 *Member, System-Wide Bioethics Resource Service*
- 2009-2012 *Member, Pediatric Guidance Council*

Primary Children's Medical Center

- 2012-2012 *Member, Shared Accountability Organization Steering Committee*
- 2009 *Member, H1N1 and Winter Surge Executive Planning Team*
- 2005-2010 *Member, Continuing Medical Education Committee*
- 2005-2010 *Member, Grand Rounds Planning Committee*
- 2003-2012 *Member, Ethics Committee*

ACTIVE MEMBERSHIPS IN PROFESSIONAL SOCIETIES

- 2012-Present Association of Bioethics Program Directors
- 2011-Present Society for Pediatric Research
- 2000-Present American Academy of Pediatrics
- 1999-Present American Society of Bioethics and Humanities

FUNDING**Past Grants**

- 2015-2019 "Better Outcomes for Children: Promoting Excellence in Healthcare Genomics to Inform Policy."
- Percent Effort: 9%
- National Human Genome Research Institute
- Grant Number: 1U01 HG008666-01
- Role: Investigator

- 2015-2016 “Ethics of Informed Consent for Youth in Foster Care”
 Direct Costs: \$10,000
 Ethics Grant, Center for Clinical and Translational Science and Training
 University of Cincinnati Academic Health Center
 Role: Co-Investigator
- 2014-2015 “Extreme Personal Exposure Biomarker Levels: Engaging Community
 Physicians and Ethicists for Guidance”
 Direct Costs: \$11,640
 Center for Environmental Genetics
 University of Cincinnati College of Medicine
 Role: Investigator
- 2014-2015 “Child, Adolescent, and Parent Opinions on Disclosure Policies for
 Incidental Findings in Clinical Whole Exome Sequencing”
 Direct Costs: \$4,434
 Ethics Grant, Center for Clinical and Translational Science and Training,
 University of Cincinnati Academic Health Center
 Role: Principal Investigator
- 2013-2014 “Better Outcomes for Children: GWAS & PheWAS in eMERGE II
 Percent Effort: 5%
 National Human Genome Research Institute
 Grant Number: 3U01HG006828-0251
 Role: Investigator
- 2004-2005 "Potential Patients' Knowledge, Attitudes, and Beliefs Regarding
 Participating in Medical Education: Can They be Interpreted in Terms of
 Presumed Consent?"
 Direct Costs: \$8,000
 Interdisciplinary Research in Applied Ethics and Human Values, University
 Research Committee, University of Utah
 Role: Principal Investigator

TEACHING RESPONSIBILITIES/ASSIGNMENTS

Course and Curriculum Development

- 2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of
 Medicine, Taught 1 time per year, Taken by medical students, Enrollment
 100

Course Lectures

2018, 2021	Introduction to Biotechnology, “Ethics and Biotechnology” and “Clinical Ethics,” BIOL 3027, University of Cincinnati, Taught 1 time per year, Taken by undergraduate students, Enrollment 25.
2018-Present	Biomedical Ethics, “Conscientious Objection in Healthcare” and “Ethical Issues in the Care of Transgender Adolescents,” MEDS 4035 & MEDS 4036, University of Cincinnati College of Medicine, Taught 1 time per year, Taken by senior undergraduate students, Enrollment 52.
2016	Foundations of Healthcare Ethics and Law, “Clinical Ethics,” HESA 390, Xavier University.
2014-Present	Physicians and Society, “Transfusion and the Jehovah’s Witness Faith,” “Obesity Management: Ethics, Policy, and Physician Implicit Bias,” “Embryos and Ethics: The Ethics of Designer Babies,” “Ethics and Genetic Testing,” and “Ethics and Direct to Consumer Genetic Testing,” 26950112 and 26950116, University of Cincinnati School of Medicine, Taken by first and second year medical students, Enrollment 100.
2014-Present	Ethical Issues in Health Care, “Ethical Issues in Managing Drug Shortages: The Macro, Meso, and Micro Levels,” HESA 583, College of Social Sciences, Health, and Education Health Services Administration, Xavier University, Taken by health services administration students, Enrollment 25.
2009	Physical Diagnosis II, Internal Medicine 7160, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100
2003-2012	Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by fourth year medical students, Enrollment 100

Small Group Teaching

2018-Present	Ethics in Research, GNTD 7003-001, University of Cincinnati School of Medicine, Taught 1 time per year, Taken by fellows, MS, and PhD students, Enrollment 110.
2007	Physical Diagnosis I, Internal Medicine 7150, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100
2003-2012	Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by fourth medical students, Enrollment 100
2003	Pediatric Organ System, Pediatrics 7020, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

Graduate Student Committees

- 2018-2022 *Chair*, Scholarship Oversight Committee, William Sveen, Pediatric Critical Care Fellowship, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
- 2018-2020 *Member*, Scholarship Oversight Committee, Anne Heueman, Genetic Counseling, University of Cincinnati, Cincinnati, OH
- 2017-2019 *Chair*, Scholarship Oversight Committee, Bryana Rivers, Genetic Counseling, University of Cincinnati, Cincinnati, OH
- 2013-2015 *Mentor*, Sophia Hufnagel, Combined Pediatrics/Genetics Residency, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
- 2013-2015 *Co-Chair*, Scholarship Oversight Committee, Andrea Murad, Genetic Counseling, University of Cincinnati, Cincinnati, OH
- 2013-2014 *Member*, Scholarship Oversight Committee, Grace Tran, Genetic Counseling, University of Cincinnati, Cincinnati, OH
- 2011-2012 *Chair*, Scholarship Oversight Committee, Kevin E. Nelson, MD, PhD, Pediatric Inpatient Medicine Fellowship, University of Utah, Salt Lake City, UT

Continuing Education Lectures

- 2008 *Choosing Healthplans All Together (CHAT) Exercise Facilitator*, 18th Annual Intermountain Medical Ethics Conference, "Setting Priorities for Healthcare in Utah: What Choices are We Ready to Make?," Salt Lake City, Utah, October 3.
- 2007 *Speaker*, Infant Medical Surgical Unit, Primary Children's Medical Center, "Withholding and Withdrawing Artificial Nutrition and Hydration: Can It Be Consistent With Care?," Salt Lake City, Utah, September 6.
- 2007 *Faculty Scholar-in Residence*, Summer Seminar, "The Role of Religion in Bioethics," Utah Valley State College, Orem, Utah, May 1.
- 2006 *Workshop Leader*, Faculty Education Retreat, "Publications and Publishing in Medical Education," University of Utah School of Medicine, Salt Lake City, Utah, September 15.
- 2006 *Breakout Session*, 16th Annual Intermountain Medical Ethics Conference, "Donation after Cardiac Death: Evolution of a Policy," Salt Lake City, Utah, March 28.

Other Educational Activities

- 2008 *Instructor*, Contemporary Ethical Issues in Medicine and Medical Research, Osher Lifelong Learning Institute, University of Utah, "Religion and Bioethics: Religiously Based Demands for and Refusals of Treatment," Salt Lake City, Utah, February 7.
- 2007 *Speaker*, Biology Seminar, Utah Valley State College, "Is He Dead?: Criteria of the Determination of Death and Their Implications for Withdrawing Treatment and Recovering Organs for Transplant," Orem, Utah, September 21.

PEER-REVIEWED JOURNAL ARTICLES

1. Erica K. Salter, D. Micah Hester, Lou Vinarcsik, Armand H. Matheny Antommara, Johan Bester, Jeffrey Blustein, Ellen Wright Clayton, Douglas S. Diekema, Ana S. Iltis, Loretta M. Kopelman, Jay R. Malone, Mark R. Mercurio, Mark C. Navin, Erin Talati Paquette, Thaddeus Mason Pope, Rosamond Rhodes, and Lainie F. Ross, (2023) "Pediatric Decision Making: Consensus Recommendations," *Pediatrics*. 152: e2023061832. PMID: 37555276.
2. William N. Sveen, Armand H. Matheny Antommara, Stephen Gilene, and Erika L. Stalets. (2023) "Adverse Events During Apnea Testing for the Determination of Death by Neurologic Criteria: A Single Center, Retrospective Pediatric Cohort." *Pediatric Critical Care Medicine*. 24: 399-405. PMID: 36815829.
3. Erica K. Salter, Jay R. Malone, Amanda Berg, Annie Friedrich, Alexandra Hucker, Hillary King, and Armand H. Matheny Antommara. (2023) "Triage Policies at U.S. Hospitals with Pediatric Intensive Care Units." *AJOB Empirical Bioethics*. 14: 84-90. PMID: 36576201.
4. Armand H. Matheny Antommara, Elizabeth Lanphier, Anne Housholder, and Michelle McGowan. (2023). "A mixed methods analysis of requests for religious exemptions to a COVID-19 vaccine requirement." *AJOB Empirical Bioethics*. 14: 15-22. PMID: 36161802.
5. Anne C Heuerman, Danielle Bessett, Armand H. Matheny Antommara, Leandra. K. Toluoso, Nicki Smith, Alison H. Norris and Michelle L. McGowan (2022). "Experiences of reproductive genetic counselors with abortion regulations in Ohio." *Journal of Genetic Counseling*. 31: 641-652. PMID: 34755409.
6. Armand H. Matheny Antommara and Ndidi I. Unaka. (2021) "Counterpoint: Prioritizing Health Care Workers for Scarce Critical Care Resources is Impractical and Unjust." *Journal of Hospital Medicine*. 16: 182-3. PMID 33617445.
7. Gregory A. Grabowski, Armand H. Matheny Antommara, Edwin H. Kolodny, and Pramod K. Mistry. (2021) "Gaucher Disease: Basic and Translational Science Needs for More Complete Therapy and Management." *Molecular Genetics and Metabolism*. 132: 59-75. PMID: 33419694.
8. Armand H. Matheny Antommara, Laura Monhollen, and Joshua K. Schaffzin. (2021) "An Ethical Analysis of Hospital Visitor Restrictions and Masking Requirements During the COVID-19." *Journal of Clinical Ethics*. 32(1): 35-44. PMID 33416516.
9. Armand H. Matheny Antommara (2020) "The Pediatric Hospital Medicine Core Competencies: 4.05 Ethics." *Journal of Hospital Medicine*. 15(S1): 120-121.
10. Armand H. Matheny Antommara, Tyler S. Gibb, Amy L. McGuire, Paul Root Wolpe, Matthew K. Wynia, Megan K. Applewhite, Arthur Caplan, Douglas S. Diekema, D. Micah Hester, Lisa Soleymani Lehmann, Renee McLeod-Sordjan, Tamar Schiff, Holly K. Tabor, Sarah E. Wieten, and Jason T. Eberl for a Task Force of the Association of Bioethics Program Directors (2020) "Ventilator Triage Policies During the COVID-19 Pandemic at U.S. Hospitals Associated With Members of the

- Association of Bioethics Program Directors.” *Annals of Internal Medicine*. 173(3): 188-194. PMID: 32330224.
11. Armand H. Matheny Antommara (2020) “Conflicting Duties and Reciprocal Obligations During a Pandemic.” *Journal of Hospital Medicine*. 5:284-286. PMID: 32379030.
 12. Mary V. Greiner, Sarah J. Beal, and Armand H. Matheny Antommara (2020) “Perspectives on Informed Consent Practices for Minimal-Risk Research Involving Foster Youth.” *Pediatrics*. 45:e20192845. PMID: 32156772.
 13. Jennifer deSante-Bertkau, Michelle McGowan, and Armand H. Matheny Antommara (2018) “Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations.” *Journal of Clinical Ethics*. 29:291-304. PMID: 30605439.
 14. Andrew J. Redmann, Melissa Schopper, Armand H. Matheny Antommara, Judith Ragsdale, Alessandro de Alarcon, Michael J. Jutter, Catherine K. Hart, and Charles M. Myer. (2018) “To Transfuse or Not to Transfuse? Jehovah’s Witnesses and PostOperative Hemorrhage in Pediatric Otolaryngology.” *International Journal of Pediatric Otorhinolaryngology*. 115:188-192. PMID: 30368384.
 15. Armand H. Matheny Antommara, Kyle B. Brothers, John A. Myers, Yana B Feygin, Sharon A. Aufox, Murray H. Brilliant, Pat Conway, Stephanie M. Fullerton, Nanibaa’ A. Garrison, Carol R. Horowitz, Gail P. Jarvik, Rongling Li, Evette J. Ludman, Catherine A. McCarty, Jennifer B. McCormick, Nathaniel D. Mercaldo, Melanie F. Myers, Saskia C. Sanderson, Martha J. Shrubsole, Jonathan S. Schildcrout, Janet L. Williams, Maureen E. Smith, Ellen Wright Clayton, Ingrid A. Holm. (2018) “Parents’ Attitudes toward Consent and Data Sharing in Biobanks: A Multi-Site Experimental Survey.” *AJOB Empirical Research*. 21:1-15. PMID: 30240342.
 16. Armand H. Matheny Antommara and Cynthia A. Prows. (2018) “Content Analysis of Requests for Religious Exemptions from a Mandatory Influenza Vaccination Program for Healthcare Personnel” *Journal of Medical Ethics*. 44: 389-391. PMID: 29463693.
 17. Armand H. Matheny Antommara (2017) “May Medical Centers Give Nonresident Patients Priority in Scheduling Outpatient Follow-Up Appointments?” *Journal of Clinical Ethics*. 28: 217-221. PMID: 28930708.
 18. Andrea M. Murad, Melanie F. Myers, Susan D. Thompson, Rachel Fisher, and Armand H. Matheny Antommara (2017) “A Qualitative Study of Adolescents’ Understanding of Biobanks and Their Attitudes Toward Participation, Re-contact, and Data Sharing.” *American Journal of Medical Genetics: Part A*. 173: 930-937. PMID: 28328120.
 19. Saskia Sanderson, Kyle Borthers, Nathaniel Mercaldo, Ellen Wright Clayton, Armand Antommara, Sharon Aufox, Murray Brilliant, Diego Campos, David Carrell, John Connolly, Pat Conway, Stephanie Fullerton, Nanibaa Garrison, Carol Horowitz, Gail Jarvik, David Kaufman, Terrie Kitchner, Rongling Li, Evette Ludman, Catherine McCarty, Jennifer McCormick, Valerie McManus, Melanie Myers, Aaron Scrol, Janet Williams, Martha Shrubsole, Jonathan Schildcrout, Maureen Smith, and Ingrid Holm (2017) “Public Attitudes Towards Consent and Data Sharing in Biobank Research: A

- Large Multisite Experimental Survey in the US.” *The American Journal of Human Genetics*. 100: 414-427. PMID: 28190457.
20. Maureen E. Smith, Saskia C Sanderson, Kyle B Brothers, Melanie F Myers, Jennifer McCormick, Sharon A Aufox, Martha J Shrubsole, Nanibaa' A Garrison, Nathaniel D Mercaldo, Jonathan S Schildcrout, Ellen Wright Clayton, Armand H. Matheny Antommara, Melissa Basford, Murray Brilliant, John J Connolly, Stephanie M Fullerton, Carol R Horowitz, Gail P Jarvik, Dave Kaufman, Terrie Kitchner, Rongling Li, Evette J Ludman, Catherine McCarty, Valerie McManus, Sarah C Stallings, Janet L Williams, and Ingrid A Holm (2016) “Conducting a Large, Multi-Site Survey about Patients' Views on Broad Consent: Challenges and Solutions.” *BMC Medical Research Methodology*. 16: 162. PMID: 27881091.
 21. Angela Lorts, Thomas D. Ryan, Armand H. Matheny Antommara, Michael Lake, and John Bucuvalas (2016) “Obtaining Consensus Regarding International Transplantation Continues to be Difficult for Pediatric Centers in the United States.” *Pediatric Transplant*. 20: 774-777. PMID: 27477950.
 22. Sophia B. Hufnagel, Lisa J. Martin, Amy Cassedy, Robert J. Hopkin, and Armand H. Matheny Antommara (2016) “Adolescents' Preferences Regarding Disclosure of Incidental Findings in Genomic Sequencing That Are Not Medically Actionable in Childhood.” *American Journal of Medical Genetics Part A*. 170: 2083-2088. PMID: 27149544.
 23. Nanibaa' A. Garrison, Nila A. Sathe, Armand H. Matheny Antommara, Ingrid A. Holm, Saskia Sanderson, Maureen E. Smith, Melissa McPheeters, and Ellen Wright Clayton (2016) “A Systematic Literature Review of Individuals' Perspectives on Broad Consent and Data Sharing in the United States.” *Genetics in Medicine*. 18: 663-71. PMID: 26583683.
 24. Kyle B. Brothers, Ingrid A. Holm Janet E. Childerhose, Armand H. Matheny Antommara, Barbara A. Bernhardt, Ellen Wright Clayton, Bruce D. Gelb, Steven Joffe, John A. Lynch, Jennifer B. McCormick, Laurence B. McCullough, D. William Parsons, Agnes S. Sundaresan, Wendy A. Wolf, Joon-Ho Yu, and Benjamin S. Wilfond (2016) “When Genomic Research Participants Grow Up: Contact and Consent at the Age of Majority.” *The Journal of Pediatrics* 168: 226-31. PMID: 26477867.
 25. Erin E. Bennett, Jill Sweney, Cecile Aguayo, Criag Myrick, Armand H. Matheny Antommara, and Susan L. Bratton (2015) “Pediatric Organ Donation Potential at a Children's Hospital.” *Pediatric Critical Care Medicine*. 16: 814-820. PMID: 26237656.
 26. Anita J. Tarzian, Lucia D. Wocial, and the ASBH Clinical Ethics Consultation Affairs Committee (2015) “A Code of Ethics for Health Care Ethics Consultants: Journey to the Present and Implications for the Field.” *American Journal of Bioethics*. 15: 38-51. PMID: 25970392.

27. Armand H. Matheny Antommarrina, Christopher A. Collura, Ryan M. Antiel, and John D. Lantos (2015) "Two Infants, Same Prognosis, Different Parental Preferences." *Pediatrics*, 135: 918-923. PMID: 25847802.
28. Stefanie Benoit, Armand H. Matheny Antommarrina, Norbert Weidner, and Angela Lorts (2015) "Difficult Decision: What should we do when a VAD supported child experiences a severe stroke?" *Pediatric Transplantation* 19: 139-43. PMID: 25557132.
29. Kyle B. Brothers, John A. Lynch, Sharon A. Aufox, John J. Connolly, Bruce D. Gelb, Ingrid A. Holm, Saskia C. Sanderson, Jennifer B. McCormick, Janet L. Williams, Wendy A. Wolf, Armand H. Matheny Antommarrina, and Ellen W. Clayton (2014) "Practical Guidance on Informed Consent for Pediatric Participants in a Biorepository." *Mayo Clinic Proceedings*, 89: 1471-80. PMID: 25264176.
30. Sophia M. Bous Hufnagel and Armand H. Matheny Antommarrina (2014) "Laboratory Policies on Reporting Secondary Findings in Clinical Whole Exome Sequencing: Initial Uptake of the ACMG's Recommendations." *American Journal of Medical Genetics Part A*, 164: 1328-31. PMID: 24458369.
31. Wylie Burke, Armand H. Matheny Antommarrina, Robin Bennett, Jeffrey Botkin, Ellen Wright Clayton, Gail E. Henderson, Ingrid A. Holm, Gail P. Jarvik, Muin J. Khoury, Bartha Maria Knoppers, Nancy A. Press, Lainie Friedman Ross, Mark A. Rothstein, Howard Saal, Wendy R. Uhlmann, Benjamin Wilfond, Susan M. Wold, and Ron Zimmern (2013) "Recommendations for Returning Genomic Incidental Findings? We Need to Talk!" *Genetics in Medicine*, 15: 854-859. PMID: 23907645.
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Newspaper Articles

1. W. Bradley Poss and Armand H. Matheny Antommara (2010) “Mass casualty planning must incorporate needs of children.” *AAP News* 31 (July): 38.
2. Robert Murray and Armand H. Matheny Antommara (2010) “Pediatricians should work with school nurses to develop action plans for children with DNAR orders.” *AAP News* 31 (May): 30..
3. Armand H. Matheny Antommara (2009) “Addressing physicians’ conscientious objections in health care.” *AAP News* 30 (December): 32.

UNPUBLISHED POSTER PRESENTATIONS

1. Armand H. Matheny Antommara. (2018) “Ethical Issues in the Care of International Patients: A Case Study.” International Conference on Clinical Ethics and Consultation, Oxford, United Kingdom.
1. Jill S Sweney, Brad Poss, Colin Grissom, Brent Wallace, and Armand H Matheny Antommara, (2010) “Development of a Statewide Pediatric Pandemic Triage Plan in Utah.” Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20103713.147.
2. Christopher G. Maloney, Armand H. Matheny Antommara, James F. Bale, Thomas Greene, Jian Ying, Gena Fletcher, and Rajendu Srivastava (2010) “Why Do Pediatric Interns Violate the 30 Hour Work Rule?” Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20101500.596
3. Armand H. Matheny Antommara and Edward B. Clark (2007) “Resolving Conflict through Bioethics Mediation.” 3rd International Conference on Ethics Consultation and Clinical Ethics, Toronto, Canada.
4. Elizabeth Tyson, Tracy Hill, Armand Antommara, Gena Fletcher, and Flory Nkoy (2007) “Physician Practice Patterns Regarding Nasogastric Feeding Supplementation and Intravenous Fluids in Bronchiolitis Patients.” Pediatrics Academic Societies Annual Meeting, Toronto, Canada. E-PAS2007:61300.

ORAL PRESENTATIONS

Keynote/Plenary Lectures

International

1. 2021, *Panelist*, Partnership for Quality Medical Donations, Charitable Access Programming for Rare Diseases, “Ethical Issues,” Webinar, April 6.
2. 2017, *Invited Speaker*, Spina Bifida Fetoscopic Repair Study Group and Consortium, “Ethics of Innovation and Research in Fetal Surgery,” Cincinnati, Ohio, October 26.
3. 2014, *Invited Speaker*, CIC 2013 CCI: Canadian Immunization Conference, “Condition-of-Service Influenza Prevention in Health Care Settings,” Ottawa, Canada, December 2.
4. 2014, *Invited Speaker*, National Conference of the Chinese Pediatric Society, “A Brief Introduction to Pediatric Research and Clinical Ethics,” Chongqing, China, September 12.

National

1. 2020, *Panelist*, Children's Mercy Bioethics Center, "Ethical Issues in the COVID Pandemic at Children's Hospitals," Webinar, March 2.
2. 2019, *Invited Speaker*, North American Fetal Therapy Network (NAFTnet), "Ethics of Innovation," Chicago, Illinois, October 12.
3. 2019, *Panelist*, National Society of Genetic Counselors Prenatal Special Interest Group, "Fetal Intervention Ethics," Webinar, September 12.
4. 2017, *Invited Participant*, American College of Epidemiology Annual Meeting, Preconference Workshop, "Extreme Personal Exposure Biomarker Levels: Guidance for Study Investigators," New Orleans, Louisiana, September 24.
5. 2016, *Invited Speaker*, American Academy of Pediatrics National Conference & Exhibition, Joint Program: Section on Hospital Medicine and Section on Bioethics, "Resource Allocation: Do We Spend Money to Save One Patient with Ebola or Over a 1,000?" San Francisco, California, October 23.
6. 2016, *Invited Speaker*, 26th Annual Specialist Education in Extracorporeal Membrane Oxygenation (SEECHMO) Conference, "Ethical Issues in ECMO: The Bridge to Nowhere," Cincinnati, Ohio, June 5.
7. 2015, *Invited Speaker*, Extracorporeal Life Support Organization (ELSO) 26th Annual Conference, "ECMO-Supported Donation after Circulatory Death: An Ethical Analysis," Atlanta, Georgia, September 20.
8. 2014, *Invited Speaker*, Pediatric Evidence-Based Practice 2014 Conference: Evidence Implementation for Changing Models of Pediatric Health Care, "Ethical Issues in Evidence-Based Practice," Cincinnati, Ohio, September 19.
9. 2014, *Invited Speaker*, 6th Annual David Kline Symposium on Public Philosophy: Exploring the Synergy Between Pediatric Bioethics and Child Rights, "Does Predictive Genetic Testing for Adult Onset Conditions that Are Not Medically Actionable in Childhood Violate Children's Rights?" Jacksonville, Florida, March 6.
10. 2010, *Invited Speaker*, Quest for Research Excellence: The Intersection of Standards, Culture and Ethics in Childhood Obesity, "Research Integrity and Religious Issues in Childhood Obesity Research," Denver, Colorado, April 21.
11. 2010, *Invited Speaker*, Symposium on the Future of Rights of Conscience in Health Care: Legal and Ethical Perspectives, J. Reuben Clark Law School at Brigham Young University and the Ave Maria School of Law, "Conscientious Objection in Clinical Practice: Disclosure, Consent, Referral, and Emergency Treatment," Provo, Utah, February 26.
12. 2009, *Invited Speaker*, Pediatric Organ Donation Summit, "Research Findings Regarding Variations in Pediatric Hospital Donation after Cardiac Death Policies," Chicago, Illinois, August 18.
13. 2008, *Meet-the-Experts*, American Academy of Pediatrics National Conference & Exhibition, "Physician Refusal to Provide Treatment: What are the ethical issues?" Boston, Massachusetts, October 11.

14. 2008, *Invited Conference Faulty*, Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy, The MacLean Center for Clinical Medical Ethics at the University of Chicago, “Defending Positions or Identifying Interests: The Uses of Ethical Argumentation in the Debate over Conscience in Clinical Practice,” Chicago, IL, March 18.
15. 2007, *Symposium Speaker*, Alternative Dispute Resolution Strategies in End-of-Life Decisions, The Ohio State University Mortiz College of Law, “The Representation of Children in Disputes at the End-of-Life,” Columbus, Ohio, January 18.
16. 2005, *Keynote Speaker*, Decisions and Families, *Journal of Law and Family Studies* and The University of Utah S.J. Quinney College of Law, “Jehovah’s Witnesses, Roman Catholicism, and Calvinism: Religion and State Intervention in Parental, Medical Decision-Making,” Salt Lake City, Utah, September 23.

Regional/Local

1. 2023, *Speaker*, Yale Ethics Program, Yale School of Medicine, “Gender-Affirming Care,” New Haven, Connecticut, March 8.
2. 2021, *Panelist*, Pediatric Residency Noon Conference, University of Tennessee Health Science Center, “Bioethics Rounds—Ethical Issues in the Care of Transgender Adolescents,” Memphis, Tennessee, September 21.
3. 2020, *Keynote Speaker*, 53rd Annual Clinical Advances in Pediatrics, “Referral to a Fetal Care Center: How You Can Help Patients’ Mothers Address the Ethical Issues,” Kansas City, Kansas, September 16.
4. 2019, *Speaker*, Patient and Family Support Services, Primary Children’s Hospital, “Ethical Issues in the Care of Trans Adolescents,” Salt Lake City, Utah, December 5.
5. 2019, *Speaker*, Evening Ethics, Program in Medical Ethics and Humanities, University of Utah School of Medicine, “Patients, Parents, and Professionals: Ethical Issues in the Treatment of Trans Adolescents,” Salt Lake City, Utah, December 4.
6. 2019, *Speaker*, Pediatric Hospital Medicine Board Review Course, “Ethics, Legal Issues, and Human Rights including Ethics in Research,” Cincinnati, Ohio, September 8.
7. 2019, *Speaker*, Advances in Fetology, “Evolving Attitudes Toward the Treatment of Children with Trisomies,” Cincinnati, Ohio, September 6.
8. 2019, *Speaker*, Half-Day Ethics Training: Ethics Consultation & Ethics Committees, “Navigating the Rapids of Clinical Ethics Consultation: Intake, Recommendations, and Documentation,” Salt Lake City, Utah, June 1.
9. 2019, *Speaker*, Scientific and Ethical Underpinnings of Gene Transfer/Therapy in Vulnerable Populations: Considerations Supporting Novel Treatments, BioNJ, “What Next? An Ethical analysis of Prioritizing Conditions and Populations for Developing Novel Therapies,” Cranbury, New Jersey, March 7.
10. 2018, *Panelist*, Periviability, 17th Annual Regional Perinatal Summit, Cincinnati, Ohio, October 12.

11. 2018, *Speaker*, Regional Advance Practice Registered Nurse (APRN) Conference, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati, Ohio, April 26.
12. 2018, *Speaker*, Southern Ohio/Northern Kentucky Sigma Theta Tau International Annual Conference, "Between Hope and Hype: Ethical Issues in Precision Medicine," Sharonville, Ohio, March 2.
13. 2017, *Speaker*, Advances in Fetology 2017, "Ethics of Innovation and Research: Special Considerations in Fetal Therapy Centers," Cincinnati, Ohio, October 27.
14. 2016, *Speaker*, End-of-Life Pediatric Palliative Care Regional Conference, "Ethical/Legal Issues in Pediatric Palliative Care," Cincinnati, Ohio, September 15.
15. 2016, *Speaker*, 26th Annual Bioethics Network of Ohio (BENO) Conference, "When Does Parental Refusal of Medical Treatment for Religious Reasons Constitute Neglect?" Dublin, Ohio, May 29.
16. 2014, *Speaker*, Cincinnati Comprehensive Sickle Cell Center Symposium: Research Ethics of Hydroxyurea Therapy for Sickle Cell Disease During Pregnancy and Lactation, "Ethical Issues in Research with Pregnant and Lactating Women," Cincinnati, Ohio, October 30.
17. 2014, *Speaker*, Advances in Fetology 2014, "The 'Miracle Baby' and Other Cases for Discussion," Cincinnati, Ohio, September 26.
18. 2014, *Speaker*, Advances in Fetology 2014, "'Can you tell me ...?': Achieving Informed Consent Given the Prevalence of Low Health Literacy," Cincinnati, Ohio, September 26.
19. 2014, *Panelist*, Center for Clinical & Translational Science & Training, Secrets of the Dead: The Ethics of Sharing their Data, Cincinnati, Ohio, August 28.
20. 2014, *Speaker*, Office for Human Research Protections Research Community Forum: Clinical Research ... and All That Regulatory Jazz, "Research Results and Incidental Findings: Do Investigators Have a Duty to Return Results to Participants," Cincinnati, Ohio, May 21.
21. 2013, *Opening Presentation*, Empirical Bioethics: Emerging Trends for the 21st Century, University of Cincinnati Center for Clinical & Translational Science & Training, "Empirical vs. Normative Ethics: A Comparison of Methods," Cincinnati, Ohio, February 21.
22. 2012, *Videoconference*, New York State Task Force on Life and the Law, "Pediatric Critical Care Triage," New York, New York, March 1.
23. 2011, *Presenter*, Fall Faculty Development Workshop, College of Social Work, University of Utah, "Teaching Ethics to Students in the Professions," Salt Lake City, Utah, November 14.
24. 2011, *Speaker*, 15th Annual Conference, Utah Chapter of the National Association of Pediatric Nurse Practitioners, "Ethical Issues in Pediatric Practice," Salt Lake City, Utah, September 22.
25. 2011, *Speaker*, Code Silver! Active Shooter in the Hospital, Utah Hospitals & Health Systems Association, Salt Lake City, Utah, March 21.

26. 2009, *Speaker*, Medical Staff Leadership Conference, Intermountain Healthcare, “The Ethics of Leadership,” Park City, Utah, October 30.
27. 2008, *Speaker*, The Art and Medicine of Caring: Supporting Hope for Children and Families, Primary Children’s Medical Center, “Medically Provided Hydration and Nutrition: Ethical Considerations,” Salt Lake City, Utah, February 25.
28. 2005, *Speaker*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners) Chapter Pharmacology and Pediatric Conference, “Immunization Update,” Salt Lake City, Utah, August 18.
29. 2005, *Keynote Speaker*, 17th Annual Conference, Utah Society for Social Work Leadership in Health Care, “Brain Death: Accommodation and Consultation,” Salt Lake City, March 18.
30. 2004, *Continuing Education Presentation*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners), “Febrile Seizures,” Salt Lake City, Utah, April 22.
31. 2004, *Speaker*, Advocacy Workshop for Primary Care Providers, “Ethics of Advocacy,” Park City, Utah, April 3.
32. 2002, *Speaker*, 16th Annual Biologic Basis of Pediatric Practice Symposium, “Stem Cells: Religious Perspectives,” Deer Valley, Utah, September 14.

Meeting Presentations

International

1. 2023, *Speaker*, International Conference on Clinical Ethics and Consultation, “Addressing Ethical and Conceptual Issues in Gender-Affirming Medical Care Outside of the Hospital,” Rome, Italy, June 8.
2. 2018, *Speaker*, International Conference on Clinical Ethics and Consultation, “A Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations,” Oxford, United Kingdom, June 21.

National

1. 2023, Kelsey S. Ryan, Rakhi Gupta Bassuray, Leela Sarathy, Sharon Ostfeld, Armand H. Matheny Antommara, Erin Rholl, Steven R. Leuthner, and Christy L. Cummings. *Workshop Presenter*, Pediatric Academic Societies Annual Meeting, “How Can Newborn Toxicology Testing be Equitable?” Washington, DC, April 30.
2. 2022, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, “A Mixed Methods Analysis of Requests for Religious Exemptions to a COVID-19 Vaccine Requirement.” Portland, Oregon, October 27.
3. 2022, *Panelist*, American Society for Bioethics and Humanities Annual Meeting, Pediatric Ethics Affinity Group, “When Ethical Healthcare Is Prohibited By Law, How Do We Respond?” Portland, Oregon, October 27.
4. 2022, *Speaker*, APPD/PAS Fellow Core Curriculum Workshop, Pediatric Academic Societies Annual Meeting, “From Idea to Implementation: Navigating the Ethical Landscape of Pediatric Clinical Research,” Denver, Colorado, April 22.

5. 2021, *Panelist*, Pediatric Endocrine Society Annual Meeting, Difference of Sex Development Special Interest Group, Virtual Conference, April 29.
6. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Is This Child Dead? Controversies Regarding the Neurological Criteria for Death," Virtual Conference, October 17.
7. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Contemporary Ethical Controversy in Fetal Therapy: Innovation, Research, Access, and Justice," Virtual Conference, October 15.
8. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "K-12 Schools and Mandatory Public Health Programs During the COVID-19 Pandemic," Virtual Conference, October 15.
9. 2019, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Issues in Translating Gene Transfer Studies Involving Children with Neurodegenerative Disorders," Pittsburgh, Pennsylvania, October 26.
10. 2019, *Moderator*, Pediatric Academic Societies Annual Meeting, Clinical Bioethics, Baltimore, Maryland, April 28.
11. 2018, *Presenter*, American Society for Bioethics and Humanities Annual Meeting, "Looking to the Past, Understanding the Present, and Imaging the Future of Bioethics and Medical Humanities' Engagement with Transgender Health," Anaheim, California, October 19.
12. 2018, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Should Vaccination Be a Prerequisite for Solid Organ Transplantation?" Anaheim, California, October 18.
13. 2018, Lindsey Douglas, Armand H. Matheny Antommaria, Derek Williams. *Workshop Presenter*, Pediatric Hospital Medicine Annual Meeting, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB)." Atlanta, Georgia, July 20.
14. 2018, Alan Schroeder, Armand H. Matheny Antommaria, Hannah Bassett, Kevin Chi, Shawn Ralston, Rebecca Blankenburg. *Workshop Speaker*, Pediatric Hospital Medicine Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Atlanta, Georgia, July 20.
15. 2018, Alan Schroeder, Hannah Bassett, Rebecca Blankenburg, Kevin Chi, Shawn Ralston, Armand H. Matheny Antommaria. *Workshop Speaker*, Pediatric Academic Societies Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Toronto, Ontario, Canada, May 7.
16. 2017, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Tensions in Informed Consent for Gender Affirming Hormone Therapy and Fertility Preservation in Transgender Adolescents," Kansas City, Missouri, October 19.
17. Lindsey Douglas, Armand H. Matheny Antommaria, and Derek Williams. 2017, *Workshop Leader*, PHM[Pediatric Hospital Medicine]2017, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB) Process," Nashville, Tennessee, July 21.

18. 2016, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Challenges in the Care of International Patients: Organization, Justice, and Cultural Considerations," Washington, DC, October 9.
19. 2015, *Coauthor*, The American Society of Human Genetics Annual Meeting, "Adolescents' Opinions on Disclosure of Non-Actionable Secondary Findings in Whole Exome Sequencing," Baltimore, Maryland, October 9.
20. 2012, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "A Public Health Ethics Analysis of the Mandatory Immunization of Healthcare Personnel: Minimizing Burdens and Increasing Fairness," Washington, DC, October 21.
21. Armand H. Matheny Antommara, Valerie Gutmann Koch, Susie A. Han, Carrie S. Zoubul. 2012, *Moderator*, American Society for Bioethics and Humanities Annual Meeting, "Representing the Underrepresented in Allocating Scarce Resources in a Public Health Emergency: Ethical and Legal Considerations," Washington, DC, October 21.
22. 2012, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of International Variation in Donation after Circulatory Death Policies and Rates," Boston, Massachusetts, April 30. Publication 3150.4.
23. 2011, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "The Intersection of Policy, Medicine, and Ethics during a Public Health Disaster: Special Considerations for Children and Families," Minneapolis, Minnesota, October 13.
24. Armand H. Matheny Antommara and Joel Frader. 2010, *Workshop Leader*, Pediatric Academic Societies Annual Meeting, "Conscientious Objection in Health Care: Respecting Conscience and Providing Access," Vancouver, British Columbia, Canada. May 1. Session 1710.
25. 2009, *Workshop Leader*, American Society for Bioethics and Humanities Annual Meeting, "Advanced Clinical Ethics Consultation Skills Workshop: Process and Interpersonal Skills," Washington, DC, October 15.
26. 2009, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of Donation after Cardiac Death Policies at Children's Hospitals," Baltimore, Maryland, May 2. Publication 2120.6.
27. 2008, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Qualitative Analysis of Donation After Cardiac Death (DCD) Policies at Children's Hospitals," Cleveland, Ohio, October 26.
28. 2007, *Participant*, Hamline University School of Law Biennial Symposium on Advanced Issues in Dispute Resolution, "An Intentional Conversation About Conflict Resolution in Health Care," Saint Paul, Minnesota, November 8-10.
29. 2007, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Consultation and Alternative Dispute Resolution: Opportunities for Collaboration," Washington, DC, October 21.

30. 2007, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "DNAR Orders in Schools: Collaborations Beyond the Hospital," Washington, DC, October 18.
31. Armand H. Matheny Antommara and Jeannie DePaulis. 2007, *Speaker*, National Association of Children's Hospitals and Related Institutions Annual Meeting, "Using Mediation to Address Conflict and Form Stronger Therapeutic Alliances," San Antonio, Texas, October 9.
32. 2006, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Mediation: A Critique," Denver, Colorado, October 28.
33. 2005, *Panelist*, American Society of Bioethics and Humanities Annual Meeting, "How I See This Case: 'He Is Not His Brain,'" Washington, DC, October 20.
34. 2005, *Paper Presentation*, Pediatric Ethics: Setting an Agenda for the Future, The Cleveland Clinic, "'He Is Not His Brain:' Accommodating Objections to 'Brain Death,'" Cleveland, Ohio, September 9.
35. 2004, *Speaker*, American Society for Bioethics and Humanities Spring Meeting, "Verification and Balance: Reporting Within the Constraints of Patient Confidentiality," San Antonio, Texas, March 13.
36. 2002, *Panelist*, American Society for Bioethics and Humanities Annual Meeting, "'Who Should Survive?:' Mental Retardation and the History of Bioethics," Baltimore, Maryland, October 24.

Invited/Visiting Professor Presentations

1. 2013, Visiting Professor, "How to Listen, Speak and Think Ethically: A Multidisciplinary Approach," Norton Suburban Hospital and Kosair Children's Hospital, Louisville, Kentucky, May 22.
2. 2010, Visiting Professor, Program in Bioethics and Humanities and Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Ethics Facilitation," University of Iowa Carver College of Medicine, Iowa City, Iowa, September 10.

Grand Round Presentations

1. 2019, David Green Lectureship, "Establishing Goals of Care and Ethically Limiting Treatment," Primary Children's Hospital, Salt Lake City, Utah, December 5.
2. 2018, "The Ethics of Medical Intervention for Transgender Youth," El Rio Health, Tucson, Arizona, September 29.
3. 2018, Pediatrics, "Patient Selection, Justice, and Cultural Difference: Ethical Issues in the Care of International Patients," Cleveland Clinic, Cleveland, Ohio, April 10.
4. 2018, Bioethics, "Reversibility, Fertility, and Conflict: Ethical Issues in the Care of Transgender and Gender Nonconforming Children and Adolescents," Cleveland Clinic, Cleveland, Ohio, April 9.

5. 2017, Heart Institute, ““Have you ever thought about what you would want—if god forbid—you became sicker?”: Talking with adult patients about advance directives,” Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, October 16.
6. 2017, Pediatrics, “Respectful, Effective Treatment of Jehovah’s Witnesses,” with Judith R. Ragsdale, PhD, MDiv and David Morales, MD, Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, March 14.
7. 2017, Pediatrics, “Ethical Dilemmas about Discharging Patients When There Are Disagreements Concerning Safety,” Seattle Children’s Hospital, Seattle, Washington, January 19.
8. 2015, Pediatrics, ““Nonbeneficial’ Treatment: What must providers offer and what can they withhold?,” Greenville Health System, Greenville, South Carolina, May 10.
9. 2014, Advance Practice Providers, “Common Ethical Issues,” Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, August 13.
10. 2014, Respiratory Therapy, “Do-Not-Resuscitate (DNR) Orders,” Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, July 15.
11. 2013, Heart Institute, “No Not Months. Twenty-Two *Years*-Old: Transiting Patients to an Adult Model of Care.” Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, October 21.
12. 2013, Division of Neonatology, “This Premature Infant Has a *BRCA1* Mutation!?: Ethical Issues in Clinical Whole Exome Sequencing for Neonatologists.” Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, October 11.
13. 2013, Department of Pediatrics, “Adults are Not Large Children: Ethical Issues in Caring for Adults in Children’s Hospitals,” Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, February 26.
14. 2012, “Mandate or Moratorium?: Persisting Ethical Controversies in Donation after Circulatory Death,” Cedars-Sinai Medical Center, Los Angeles, California, May 16.
15. 2011, Division of Pediatric Neurology Friday Lecture Series, “Inducing or Treating ‘Seizures’ with Placebos: Is It Ever Ethical?,” University of Utah, Salt Lake City, Utah, October 7.
16. 2011, Department of Surgery, “DNR Orders in the OR and other Ethical Issues in Pediatric Surgery: Case Discussions,” Primary Children’s Medical Center, Salt Lake City, Utah, October 3.
17. 2009, Department of Pediatrics, “What to Do When Parents Want Everything Done: ‘Futility’ and Bioethical Mediation,” Primary Children’s Medical Center, Salt Lake City, Utah, September 17.
18. 2008, Division of Pulmonology and Critical Care, “Futility: May Clinicians Ever Unilaterally Withhold or Withdraw Medical Treatment?” Utah Valley Regional Medical Center, Provo, Utah, April 17.
19. 2007, Division of Otolaryngology-Head and Neck Surgery, “Advance Directives, Durable Powers of Attorney for Healthcare, and Do Not Attempt Resuscitation Orders: Oh My!,” University of Utah School of Medicine, Salt Lake City, Utah, June 20.

Outreach Presentations

1. 2019, *Panelist*, Cincinnati Edition, WVXU, “The Ethics of Human Gene Editing,” Cincinnati, Ohio, June 13.
2. 2019, *Speaker*, Adult Forum, Indian Hill Church, “Medical Ethics,” Indian Hill, Ohio, March 24.
3. 2016, *Speaker*, Conversations in Bioethics: The Intersection of Biology, Technology, and Faith, Mt. Washington Presbyterian Church, “Genetic Testing,” Cincinnati, Ohio, October 12.
4. 2008, *Speaker*, Science in Society, Co-sponsored by KCPW and the City Library, “Death—Choices,” Salt Lake City, Utah, November 20.
5. 2003, *Panelist*, Utah Symposium in Science and Literature, “The Goodness Switch: What Happens to Ethics if Behavior is All in Our Brains?” Salt Lake City, Utah, October 10.
6. 2002, *Respondent*, H. Tristram Englehardt, Jr. “The Culture Wars in Bioethics,” Salt Lake Community College, Salt Lake City, Utah, March 29.

Podcasts

1. 2021, “Ethics of COVID Vaccines in Kids,” PHM from Pittsburgh, August 12.
2. 2020, COVID Quandaries: Episode 1, “Is Getting Sick Just Part of the Job?” Hard Call, October 6.

EXHIBIT B

TABLE 1: Level (Quality) of Evidence and Class (Strength) of Recommendation¹ and in 2020 American Heart Association Guideline for Pediatric Basic and Advanced Life Support

	Class 1 (Strong) Benefit >>> Risk	Class 2a (Moderate) Benefit >> Risk	Class 2b (Weak) Benefit >= Risk	Class 3 No Benefit (Moderate) Benefit = Risk	Class 3 Harm (Strong) Risk > Benefit	Total
Level A	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Level B-R (Randomized)	1 (0.8%)	2 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)
Level B-NR (Nonrandomized)	5 (3.8%)	9 (6.9%)	3 (2.3%)	0 (0.0%)	2 (1.5%)	19 (14.6%)
Level C-LD (Limited Data)	24 (18.5%)	22 (16.9%)	21 (16.2%)	1(0.8%)	2 (1.5%)	70 (53.8%)
Level C-EO (Expert Opinion)	22 (16.9%)	9 (6.9%)	6 (4.6%) ₋	0 (0.0%)	0 (0.0%)	37 (28.5%)
Total	53 (40.8%)	42 (32.3%)	30 (23.1%)	1 (0.8%)	4 (3.1%)	130 (100%)

1. Level (Quality) of Evidence

Level A

- High-quality evidence from more than 1 [Randomized Controlled Trial (RCT)]
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

Level B-R (Randomized)

- Moderate-quality evidence from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

Level B-NR (Nonrandomized)

- Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

Level C-LD (Limited Data)

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies

- Psychological or mechanistic studies in human subjects

Level C-EO (Expert Opinion)

- Consensus of expert opinion based on clinical experience

Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2020;142(16_suppl_2):S469-S523.

EXHIBIT C

TABLE 2: Strength of Recommendation and Quality of Evidence in Recommendations Made by the Endocrine Society

Strength of the Recommendation/ Quality of the Evidence ¹	Endocrine Treatment of Gender-Dysphoric/Gender-Atypical Patients	Pediatric Obesity-Assessment, Treatment, and Prevention	Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase Deficiency
Strong High	0 (0) ²	0 (0)	0 (0)
Strong Moderate	3 (11)	4 (13)	18 (33)
Strong Low	5 (18)	6 (20)	13 (25)
Strong Very Low	2 (7)	1 (3)	1 (2)
Weak High	0 (0)	0 (0)	0 (0)
Weak Moderate	0 (0)	0 (0)	2 (4)
Weak Low	9 (32)	5 (17)	4 (7)
Weak Very Low	3 (11)	12 (40)	7 (13)
Ungraded Good Practice Statement ³	6 (21)	2 (7)	9 (17)
Either Low or Very Low	19 (68)	24 (80)	25 (46)
Total	28	30	54

¹ Quality of the Evidence

High: “Consistent evidence from well-performed RCTs [Randomized Controlled Trials] or exceptionally strong evidence from unbiased observational studies”

Moderate: “Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies”

Low: “Evidence for at least one critical outcomes from observational studies, from RCTs with serious flaws, or indirect evidence”

Very Low: “Evidence for at least one of the critical outcomes from unsystematic clinical observations or very indirect evidence”

See Swiglo BA, Murad MH, Schunemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the Grading of Recommendations, Assessment, Development, and Evaluation System. *J Clin*

Endocrinol Metab. 2008;93(3):666-673.

² n (%)

³Ungraded Good Practice Statement: “Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles.” See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

Guidelines:

Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(3):709-757.

Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2018;103(11):4043-4088.